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22 **UNITED STATES DISTRICT COURT**
23 **SOUTHERN DISTRICT OF CALIFORNIA**

24 KFX MEDICAL CORP.

25 Plaintiff and Counterdefendant,

26 vs.

27 ARTHREX, INC.

28 Defendant and Counterclaimant.

Case No. 3:11-cv-1698

Hon. Dana M. Sabraw

**DEFENDANT ARTHREX, INC.'S
REQUEST FOR
RECONSIDERATION OF MOTION
IN LIMINE NO. 2**

Date: October 7, 2013

Time: 8:30 a.m.

Location: Courtroom 13A

I. INTRODUCTION

The exchange of exhibits and demonstratives to be used in the damages phase of this trial prompted Arthrex to revisit this Court's ruling on Arthrex's Motion *in Limine* No. 2 ("MIL 2") that allowed KFx to use the overturned royalty rate from Arthrex's 2008 trial with Smith & Nephew ("S&N"). Based on the arguments that were presented to the Court, it was clear that the full context of the royalty rate from the 2008 S&N trial (whose jury verdict was reversed) was not before this Court when it made its earlier decision. The subsequent proceedings in the S&N case made clear that the damage verdict from the 2008 trial was "null and void" and was considered "erased" by the district court in that case. As such, Arthrex respectfully requests reconsideration of its Motion *in Limine* No. 2.

II. KFX SHOULD BE PRECLUDED FROM USING THE ROYALTY RATE FROM THE S&N CASE BECAUSE THE RATE IS "NULL AND VOID" AND HAS BEEN "ERASED," AND IS THEREFORE IRRELEVANT UNDER FRE 402

When the Federal Circuit reversed the judgment of liability on Arthrex's appeal, *Smith & Nephew, Inc. v. Arthrex, Inc.*, 2009 WL 4282012 (Fed. Cir. 2009), the corresponding remedy for that judgment, i.e., the royalty rate, was nullified. *Wheeler v. John Deere Co.*, 935 F.2d 1090, 1096 (10th Cir. 1991) ("Reversal of a judgment and remand for a new trial places the parties in the same position, insofar as relief is concerned, as if the case had never been tried."). The district court understood this, and on remand ruled that the royalty rate was "erased." For at least this reason, the royalty rate from the S&N case is irrelevant and should be excluded under FRE 402.

The 2008 trial in the S&N case resulted in a jury verdict for S&N of infringement and damages that included a 16% royalty rate, and the court granted a permanent injunction. Ex. 1. Arthrex appealed and the Federal Circuit reversed the infringement ruling. 2009 WL 4282012 at *4. When the case went back to the district court on remand for a retrial in 2011, S&N filed a *Daubert* motion to preclude Arthrex

1 from re-litigating the 16% royalty rate (Ex. 2), and also filed a motion *in limine* to
2 preclude Arthrex from introducing evidence contrary to the court's permanent
3 injunction findings, which included findings related to the royalty rate. Ex. 3. Arthrex
4 opposed these motions and filed a counter motion *in limine* to preclude S&N from
5 using the permanent injunction findings. Exs. 4-6.

6 The Court denied S&N's motions and granted Arthrex's. Ex. 7. In doing so, the
7 Court stated that it viewed the findings from the previous trial as having been "erased,"
8 and ruled the jury should not hear the Court's findings, including the finding that the
9 jury at the 2008 trial accepted the plaintiff's suggested royalty. Ex. 8 at 11, 57, 75-76,
10 81; Ex. 9 at ¶ 37. Thus, at the 2011 retrial in the S&N case, the retrial jury never heard
11 a word about the 2008 jury's 16% reasonable royalty.

12 The court's ruling in the S&N case is consistent with the Ninth Circuit's
13 decision in *Local 159 v. Nor-Cal Plumbing, Inc.*, Nos. 96-16172 and -16284, 1999
14 U.S. App. LEXIS 17968, at *36-37 (9th Cir. July 27, 1999). In that case, the district
15 court had granted summary judgment in plaintiff's favor, and damages were awarded.
16 The defendant appealed the grant of summary judgment, but not the compensatory
17 damage award. *UA Local 343 of the United Ass'n of Journeymen & Apprentices of the*
18 *Plumbing & Pipefitting Indus. v. Nor-Cal Plumbing, Inc.*, 48 F.3d 1465, 1469 (9th Cir.
19 1995). The trial on remand involved both liability and damages. The jury found for
20 the plaintiff, but awarded less than the previous damage award. *Local 159*, 1999 U.S.
21 App. LEXIS 17968, at *37. The plaintiff appealed the damages and argued that the
22 original damages award should have been reinstated, and that the district court erred by
23 allowing the jury to decide damages anew. The Ninth Circuit rejected plaintiff's
24 argument, explaining that the earlier reversal "necessarily nullified" the first damage
25 award, and therefore, plaintiff had no right to reinstatement of damages from the earlier
26 proceeding. *Id.*

27 The Ninth Circuit's decision, relied on the Tenth Circuit's opinion in *Wheeler v.*
28 *John Deere Co.*, 935 F.2d 1090 (10th Cir. 1991). In *Wheeler*, just like in the S&N

1 case, the plaintiff won at the first trial, and the defendant appealed liability, but not
 2 damages. *Id.* at 1096. After liability was reversed on appeal, both liability and
 3 damages were retried. The plaintiff again won and was awarded damages, although
 4 less than at the first trial. *Id.* at 1093. The Tenth Circuit flatly rejected plaintiff's
 5 argument that the district court should have reinstated the damage award from the first
 6 trial. The Tenth Circuit held that it would be legal error to preclude relitigation of
 7 damages where a liability judgment is reversed, stating:

8 Once we reversed the original judgment incorporating the first jury's
 9 verdict and our mandate issued, the first verdict became null and void in
 10 its entirety. The district court could no more reinstate the damages
 11 portion of the first verdict than it could substitute the second jury's award
 12 with a larger sum pulled out of a magically appearing hat. *See Dr. Seuss,*
 The 500 Hats of Bartholomew Cubbins (1938).

13 *Id.* at 1096.

14 As such, the overturned royalty rate from the S&N case is "null and void," and
 15 therefore irrelevant under FRE 402. Just as the 16% finding was not referenced in the
 16 2011 retrial of the S&N case, this Court should preclude KFx from referencing the
 17 royalty rate in this case. To do otherwise would raise serious risk that any award
 18 would be based on evidence that was "necessarily nullified." *Local 159*, 1999 U.S.
 19 App. LEXIS 17968, at *37.

20 **III. KFX SHOULD BE PRECLUDED FROM USING THE ROYALTY RATE**
 21 **FROM THE S&N CASE UNDER FRE 403 BECAUSE IT WILL**
 22 **UNFAIRLY PREJUDICE ARTHREX AND CONFUSE THE JURY**

23 In denying Arthrex's MIL 2, this court allowed "limited" use of the overturned
 24 royalty rate. *See Ex. 10* at 14:18-20. This "limited" use included referencing that the
 25 overturned royalty rate was for the PushLock anchor and that it involved Arthrex and a
 26 competitor, but the "limited" use excluded discussing "jury findings or verdicts,"
 27 which the Court thought would be "unfairly prejudicial." *Id.* at 15:7-8; 19:3-6.

28 What has become clear, however, is that even this limited use unfairly
 prejudices Arthrex. To derive benefit from this ruling, KFx's damages expert, Mr.

1 George Strong, need only say that the 16% rate shows that his 11.7% rate is
2 reasonable. And he can say this even though the underlying verdict was reversed,
3 rendering the damages award void. To counter this simple statement, Arthrex must go
4 through the time-consuming process of discounting that rate by comparing the facts in
5 the S&N case to the facts in this case, and explain everything that happened in the
6 S&N case. With each party allowed only four hours to present its case in this trial,
7 Arthrex would be unfairly prejudiced by having to spend substantial time on this issue.
8 And even if Arthrex were to go down such a rabbit hole and distinguish the facts of the
9 S&N case from those in this case, doing so would only confuse the jury as to what the
10 real issues are in this compact trial—the appropriate damages number in *this* case.

11 KFx used this same rationale when it asked the Court to exclude Arthrex’s
12 SutureBridge patent, i.e., the ‘174 Patent, and that rationale was adopted by the Court
13 in granting KFx’s motion. KFx argued that the ‘174 Patent should be excluded under
14 FRE 403 because it would unduly prejudice KFx since “KFx will be forced to waste
15 valuable time explaining the patent’s file history, establishing the narrow scope of its
16 claims, and ensuring that the jury understands that the patent is not proof of non-
17 infringement.” Ex. 11 at 16. Counsel for KFx emphasized these reasons at oral
18 argument when he argued that admitting the ‘174 Patent would result in “one
19 confusing foray into facts.” Ex. 12 at 503:13. The Court granted KFx’s motion for
20 this very reason. *Id.* at 504:6-9 (“But seems to me ultimately that the - - for the reasons
21 set forth in the KFx briefing and just reiterated by Mr. Jennings, that there’s a host of
22 problems with the ‘174 patent coming in.”); *id.* at 526:23-527:1 (“I agree with Mr.
23 Jennings that reference to that patent would raise a host of 403 concerns and that any
24 relevance would be substantially outweighed by undue or unfair prejudice and
25 confusion of issues.”). Arthrex will similarly be “forced to waste valuable time
26 explaining” how the facts in the S&N case are different than the facts in this case,
27 resulting in a certain “confusing foray into facts.”

28 The Ninth Circuit has upheld the exclusion of evidence where, as here, its

1 admission will result in the need to conduct a “mini-trial.” *See Hodge v. Mayer*
2 *Unified School District No. 43 Governing Bd.*, 2007 WL 1112954 (9th Cir. 2007)
3 (holding that the district court did not abuse its discretion in excluding evidence under
4 Rule 403 “due to the risks of inefficiency and confusion stemming from the potential
5 need to conduct mini-trials”); *Tennison v. Circus Circus Enterprises, Inc.*, 244 F.3d
6 684, 690 (9th Cir. 2001) (upholding trial court’s exclusion of evidence that was
7 probative and not cumulative because admitting the evidence “might have resulted in a
8 ‘mini trial,’” which “would be an inefficient allocation of trial time”). Similarly,
9 evidence should be excluded where, as in this case, it causes “frolics and detours” and
10 is “likely to create side issues that would have unduly distracted the jury from the main
11 issues.” *Glaros v. H.H. Robertson Co.*, 797 F.2d 1564, 1572-73 (Fed. Cir. 1986).

12 As such, allowing KFx to use the overturned royalty rate would unfairly
13 prejudice Arthrex and confuse the jury. As such, even if the overturned royalty rate
14 has some relevance, its probative value is outweighed by its prejudice and it should be
15 excluded under FRE 403.

16
17 Respectfully submitted,

18
19 Dated: October 7, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on October 7, 2013, I caused DEFENDANT ARTHREX'S REQUEST FOR RECONSIDERATION OF MOTION *IN LIMINE* NO. 2 to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following counsel of record.

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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

KFX MEDICAL CORP.

Plaintiff and Counterdefendant,

vs.

ARTHREX, INC.

Defendant and Counterclaimant.

Case No. 3:11-cv-1698

Hon. Dana M. Sabraw

**DECLARATION OF ROBERT W.
DICKERSON, JR. IN SUPPORT OF
DEFENDANT ARTHREX, INC.'S
REQUEST FOR RECONSIDERATION
OF MOTION *IN LIMINE* NO. 2**

1 I, Robert W. Dickerson, Jr., declare and state as follows:

2 I am a partner in the law firm of Dickstein Shapiro LLP, and I am counsel of
3 record for Arthrex, Inc. (“Arthrex”) in this action. I submit this declaration in support
4 of Defendant Arthrex, Inc.’s Bench Brief on the Exclusion of S&N Evidence The
5 following statements are based on my personal knowledge.

6 1. Attached hereto as Exhibit 1 is a true and correct copy of Amended
7 Judgment issued on January 21, 2009 in Smith & Nephew, Inc. v. Arthrex Inc., Case.
8 No. 3:04-cv-0029 MO (D. Or.) (“the S&N case”) (Dkt. No. 678).

9 2. Attached hereto as Exhibit 2 is a true and correct copy of excerpts of
10 Memorandum in Support of Plaintiffs’ *Daubert* Motion for Third Trial filed May 2,
11 2011 in the S&N case (Dkt. No. 800).

12 3. Attached hereto as Exhibit 3 is a true and correct copy of excerpts of
13 Memorandum in Support of Plaintiffs’ Motion in Limine for Third Trial filed May 2,
14 2011 in the S&N case (Dkt. No. 815).

15 4. Attached hereto as Exhibit 4 is a true and correct copy of excerpts of
16 Arthrex, Inc.’s Responses to Plaintiffs’ *Daubert* Motion for Third Trial filed May 9,
17 2011 in the S&N case (Dkt. No. 851).

18 5. Attached hereto as Exhibit 5 is a true and correct copy of excerpts of
19 Arthrex, Inc.’s Responses to Plaintiffs’ Motion in Limine for Third Trial filed May 9,
20 2011 in the S&N case (Dkt. No. 850).

21 6. Attached hereto as Exhibit 6 is a true and correct copy of excerpts of
22 Memorandum in Support of Defendant’s Motion in Limine filed May 2, 2011 in the
23 S&N case (Dkt. No. 803).

24 7. Attached hereto as Exhibit 7 is a true and correct copy of Record of
25 Pretrial Conference issued on May 17, 2011 in the S&N case (Dkt. No. 868).

26 8. Attached hereto as Exhibit 8 is a true and correct copy of excerpts of the
27 Transcripts of Proceedings of the May 17, 2011 Pretrial Conference in the S&N case.
28

1 9. Attached hereto as Exhibit 9 is a true and correct copy of Statement of
2 Reasons Supporting Permanent Injunction issued on December 3, 2008 in the S&N
3 case (Dkt. No. 622).

4 10. Attached hereto as Exhibit 10 is a true and correct copy of excerpts of
5 Reporter's Transcript of Proceedings, Motion in Limine Hearing, August 9, 2013.

6 11. Attached hereto as Exhibit 11 is a true and correct copy of KFx's Trial
7 Brief Pursuant to Local Rule 16.1(f)(9)(a) filed on August 12, 2013 (Dkt. No. 202).

8 12. Attached hereto as Exhibit 12 is a true and correct copy of excerpts of the
9 trial transcript from Day 3, PM Session, August 26, 2013.

10
11 Dated: October 7, 2013

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Exhibit 1

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON**

**SMITH & NEPHEW, INC. and JOHN O.
HAYHURST, M.D.,**

Civil No. 3:04-CV-00029 MO

Plaintiffs,

AMENDED JUDGMENT

PATENT CASE

v.

ARTHREX, INC.,

Defendant.

This action came before the Court for a trial by jury. The issues have been tried and the jury rendered its verdict on June 11, 2008. In accordance with that verdict, therefore,

IT IS HEREBY ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of the plaintiffs, Smith & Nephew, Inc. and John O. Hayhurst, M.D., and against the defendant, Arthrex, Inc., that: Arthrex indirectly infringes claims 1, 2, 3, 4, 5, 6 and 7 of U.S.

Patent No. 5,601,557 ("the '557 patent") by selling or marketing its Bio-SutureTak anchors; that Arthrex indirectly infringes claims 1, 2, 3, 4, 5, 6 and 7 of the '557 patent by selling or marketing its PEEK SutureTak anchors; that Arthrex indirectly infringes claims 1, 2, 3, 4, 5, 6 and 7 of the '557 patent by selling or marketing its PEEK PushLock anchors; that Arthrex indirectly infringes claims 1, 2, 3, 4, 5, 6 and 7 of the '557 patent by selling or marketing its Bio-PushLock anchors; that Arthrex's indirect infringement of the '557 patent is willful; that based on the sales information presented at trial, the court enters judgment in favor of the plaintiffs and against defendants in the amount of \$4,788,014.00 for lost profits damages and \$9,907,844.00 for reasonable royalty damages, and the reasonable royalty rate is 16%; that plaintiffs are awarded prejudgment interest for the period up to July 31, 2008 in the amount of \$1,507,309, and that as set forth during the hearing of January 6, 2009 the Court denies supplemental damages from January 1, 2006 through June 11, 2008, and based on Arthrex sales information provided through December 31, 2008 the Court awards supplemental damages for Arthrex sales from June 12, 2008 through December 31, 2008 in the amount of \$4,045,692 and the Court also awards additional interest on plaintiffs' damages through December 31, 2008 in the amount of \$98,913, with further interest to be calculated; and further supplemental damages for Arthrex sales from January 1, 2009 and thereafter in an amount to be determined.

DATED:

21 Jan '09UNITED STATES DISTRICT JUDGE

22080241.doc

Exhibit 2

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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

SMITH & NEPHEW, INC. and

JOHN O. HAYHURST, M.D.,

Plaintiffs,

v.

ARTHREX, INC.,

Defendant.

Civil Case No. 04-00029-MO

**MEMORANDUM IN SUPPORT
OF PLAINTIFFS' DAUBERT
MOTION FOR THIRD TRIAL**

PATENT CASE

REDACTED

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10. Arthrex's New Damages Expert, David Paris, Should Not Be Allowed To Testify As To Lost Profits Before 2006, The Reasonable Royalty Rate Or Contrary To This Court's Findings Of December 3, 2008

Arthrex's original damages expert, Russell Parr, served his only expert report on July 21, 2006. (Dkt. No. 220). Mr. Parr's report was in response to the initial report of Smith & Nephew's damages expert, Richard Troxel, which covered lost profits and reasonable royalty damages for Arthrex's accused anchors from 2001 through the end of 2005. (Dkt. No. 183). Mr. Parr's responsive report also dealt with lost profits and reasonable royalty damages. Mr. Parr testified on both issues at the first trial, but at the second trial, Arthrex deliberately limited his testimony to reasonable royalty damages only, and it left Smith & Nephew's lost profits claim up through 2005 completely unchallenged, as this Court specifically found in its findings relating to the injunction (Dkt. No. 622, No. 30):

“30. This identity of form and function between the BioRaptor and Bio-SutureTak was the basis for Smith & Nephew's lost profits claim at the re-trial (Re-Trial Trans. p. 703, line 24 to p. 705, line 11 and p. 706, line 24 to p. 707, line 15, Dkt. No. 524, Exhibit 2), and the evidence on this issue was not challenged by Arthrex, either in cross-examination of Smith & Nephew's expert, Richard Troxel (*see* Re-Trial Trans. p. 734, line 18 to p. 739, line 1, Dkt. No. 524, Exhibit 2), or in the examination of its own damages expert, Russell Parr (Re-Trial Trans. p. 1089, lines 3-7; p. 1093, lines 5-18, Dkt. No. 524, Exhibit 2).”

This Court's original Judgment (Dkt. No. 598) and its amended Judgment (Dkt. No. 678) both included these lost profits damages, as well as reasonable royalty damages for that same period and a damages royalty rate of 16%. In addition to failing to contest lost profits at trial, Arthrex failed to appeal any other damages issue to the Federal Circuit. Arthrex also failed to appeal from this Court's related findings entered in connection with the permanent injunction (Dkt. No. 622).

The law of the case doctrine and mandate rule preclude any re-litigation of these issues at the third trial. This law is fully set forth in Smith & Nephew's Third Trial Memorandum. (Dkt. No. 773 pp. 7-11). For example, in *Daiichi Sankyo, Inc. v. Apotex, Inc.*, 2009 WL 1437815, at

*7-8 (D.N.J., May 19, 2009), the district court refused to re-litigate issues that were not reversed on appeal, saying:

“When a court of appeals reverses a judgment and remands for further consideration of a particular issue, leaving other determinations of the trial court intact, ***the unreversed determinations of the trial court normally continue to work an estoppel***... When the estoppel is operative in proceedings in the same case on remand, courts frequently speak in terms of the law of mandate rather than collateral estoppel but the underlying principal is the same.”
(Emphasis in original)

Here, the Federal Circuit’s mandate did not preserve certain damages issues for this Court to re-try since the issues that are foreclosed from further adjudication by the appellate court’s mandate are measured by the scope of the judgment appealed from. *See Engel Indus., Inc. v. The LockformerCo.*, 166 F.3d 1379, 1382-83 (Fed. Cir. 1999).

Accordingly, Arthrex and its new expert, Mr. Paris, should be precluded from re-litigating: 1) the amount of lost profits and reasonable royalty damages from 2001 through 2005 as found in this Court’s Judgments; and 2) the royalty rate of 16% as found in in those Judgments.¹¹ The damages issues in the third trial should be limited to infringing sales from 2006 through trial, with the 16% royalty applying to all sales for which lost profits are not found. However, as to lost profits from 2006 through trial, Arthrex’s new expert should be precluded from testifying contrary to this Court’s findings that relate to such damages, which non-appealed findings are found in this Court’s Order of December 3, 2008. (Dkt. No. 622).¹²

¹¹ The damages rate for the first and second trials was determined by both sides as a result of a hypothetical negotiation between the parties in 2001. It would apply to all infringing sales going forward, including after 2005. Arthrex’s new damages expert points to no intervening facts that would change that rate. Instead, he relies on much the same evidence Arthrex’s original expert relied upon.

¹² Those specific findings are Nos. 7, 10-16, 18-21, 23-27, 29, 30, 32, 33, 35, 36, 38, 39, 45-47, 49, 50, 54, 56, 57 and 89. (Dkt. No. 622, *see also* Joint Proposed Jury Instructions Dkt. No. 750, Smith & Nephew’s Preliminary Instructions No. 1; Smith & Nephew’s Proposed Jury Instructions Nos. 26, 36). Mr. Paris has testified at his deposition that he disagrees with a number of these.

Exhibit 3

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DISTRICT OF OREGON

PORTLAND DIVISION

SMITH & NEPHEW, INC. and

JOHN O. HAYHURST, M.D.,

Civil Case No. 04-00029-MO

Plaintiffs,

v.

ARTHREX, INC.,

Defendant.

**MEMORANDUM IN SUPPORT OF
PLAINTIFFS' MOTIONS *IN LIMINE*
FOR THIRD TRIAL**

PATENT CASE

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(Dkt. No. 712, p. 4, italicized emphasis in original, underlined emphasis added).¹⁰

In its summary judgment opposition brief, Arthrex objected to the underlined clause, arguing that “anchor resilience must be the sole cause of lodging.” (Dkt. No. 732, p. 15).

This is clearly contrary to the Federal Circuit’s decision. Moreover, it appears that Arthrex may have subsequently reconsidered its argument, since in footnote 2 of its Trial Memorandum, Arthrex stated (Dkt. No. 772, p. 1, fn. 2):¹¹

Although other factors, may contribute to lodging Arthrex’s anchors, any alleged anchor resilience alone, independent of any other factors, must be sufficient to cause lodging.

Since Arthrex apparently now may concede that other factors may supplement the lodging effect caused by resilience,¹² the Court should include Smith & Nephew’s proposed version of the “resile” and “resilience” jury instruction, and also preclude Arthrex from making any further argument that “resilience” must be the sole cause of lodging.

53. The Court Should Preclude Arthrex From Introducing Any Evidence Or Argument That Is Contrary To The Court’s Permanent Injunction Findings

After the second trial, the Court granted Smith & Nephew’s motion for a Permanent Injunction against Arthrex. (Dkt. No. 579.) On December 3, 2008, the Court issued a Statement of Reasons Supporting Permanent Injunction (Dkt. No. 622) (“the Statement”) which explained, in detail, the various findings that led the Court to issue that injunction. None of these findings were affected by the appeal to the Federal Circuit because none depended on the previous construction of “resile,” and/or because Arthrex has abandoned or waived its ability to challenge them. As a result, these findings remain valid under the doctrine of law of the case, the mandate rule, and/or issue preclusion. (See Smith & Nephew’s Trial Memorandum, Dkt. No. 773, pp. 7-11, 25).

¹⁰ Smith & Nephew proposed the same construction in the Joint Jury Instructions (Dkt. No. 750, pp. 3-4, 14, 33).

¹¹ Emphasis added here and throughout, unless otherwise noted.

¹² On the other hand, Arthrex did not agree to this relief in connection with the meet and confer on May 2, 2011, so Arthrex may still be disputing this issue.

Moreover, virtually all of these findings relate solely to damages issues that depend only on a predicate finding of infringement. *See* 35 U.S.C. §284. Thus, it would be nonsensical to argue that changing the construction of “resile” affects the Court’s finding, *e.g.*, that:

When Arthrex gained market share, it did so by taking that market share from other competitors, including Smith & Nephew and the plaintiffs’ other licensee, Johnson & Johnson (Mitek) (Re-Trial Trans. p. 765, line 22 to p. 766, line 19, Dkt. No. 524, Exhibit 2).

(Dkt. No. 622, at ¶25). Or, that:

Smith & Nephew’s lost sales extend beyond that of the suture anchors themselves, as Smith & Nephew and Arthrex both also sell drills, drill guides and other associated products for use with their suture anchors (Mahoney Decl., Dkt. No. 523, ¶ 12).

(*Id.*, at ¶36). Even those findings in the Statement that explicitly rely on a finding of infringement are unaffected by the new construction of “resile”:

Thus, Arthrex, due to its infringement, now has such a large piece of the suture anchor market and is so firmly entrenched in it that Smith & Nephew’s efforts to increase market share, despite its investment of millions of dollars in additional marketing efforts, and new product introductions, have largely been unsuccessful.

(*Id.*, at ¶44).

Arthrex’s continued infringement will result in substantially reduced sales revenue for Smith & Nephew, as well as lost market share, lost investment in new product development, lost sales of collateral products and licensing revenue, and loss of reputation, customer relationships and goodwill.

(*Id.* at ¶50).

It is also beyond dispute that Arthrex has abandoned or is precluded from raising many of its defenses, including non-infringement as to any claim limitations other than “resiles” and “resilient,” indirect infringement, willfulness, and the damages award relating to the 2001-2005 period. (*See* Dkt. No. 773, pp. 4-6). Arthrex has therefore abandoned any challenge to the findings in the Court’s Statement on these issues as well.

As a result, every single one of the Court's findings in the Statement was untouched by the appeal. However, Arthrex intends to introduce testimony to challenge many of these findings. For example, the Court has specifically found that "Arthrex and Smith & Nephew are major competitors in the market for plastic press-in suture anchors" and that "Arthrex is Smith & Nephew's biggest competitor for suture anchors throughout the United States (Re-Trial Trans. p. 265, lines 2-8, Dkt. No. 524, Exhibit 2)." (Dkt. No. 622, at ¶¶ 54, 23). The Federal Circuit's new construction of "resile" does not in any way change these facts. Yet Arthrex intends to present fact witnesses to testify to the contrary: "Smith & Nephew has never successfully penetrated the market for suture anchors" and that "competitors, such as Mitek, are positioned better than Smith & Nephew to obtain sales of suture anchors." (Dkt. No. 771, pp. 7-8). The Court also found that "Arthrex credits the Bio-SutureTak with turning around its fortunes in the suture anchor market." (Dkt. No. 622, at ¶18). Again, despite the fact that the new construction of "resile" does not alter or affect the Court's finding in any way, Arthrex now wants its fact witnesses to testify that "[the] *BioFastak* is largely responsible for Arthrex's growth of sales and market share in the resorbable shoulder fixation segment *before* Bio-SutureTak was introduced in the market." (Dkt. No. 771, p. 7; emphasis added).

Smith & Nephew respectfully submits that, in the interests of efficiency and pursuant to the doctrines of abandonment, waiver, law of the case, the mandate rule and/or issue preclusion, Arthrex should be precluded from introducing or eliciting testimony contrary to those findings.

54. This Court Should Preclude Arthrex From Introducing Any Evidence Contrary To Its Original Response To Smith & Nephew's Lost Profits Claim

While Smith & Nephew has updated its damages report to include the additional sales figures from 2005 through the projected trial date, its basic damages approach for both reasonable royalty damages and lost profits damages has remained the same, and based upon much of the same evidence as before. Arthrex, however, selected a new damages expert, David Paris, who has retracted the admissions made by Arthrex's original expert, Russell Parr (*see* Parr Rpt., Dkt. No. 220), and argued new defenses based on the same old evidence used before. None

Exhibit 4

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Case No. CV04-0029-MO

**ARTHREX, INC.'S RESPONSES TO
PLAINTIFFS' DAUBERT MOTION
FOR THIRD TRIAL**

PATENT CASE

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Response to *Daubert* 10

In this Motion, S&N is asking the Court to reinstate the damage award from the last trial (with a minor modification) and even more extreme, asking this Court to rule that the prior jury's reasonable royalty rate is established for this trial without possibility of any challenge by Arthrex. This argument is not only entirely inconsistent with what S&N told this Court a year ago, it flies in the face of all relevant law. In fact, the Ninth Circuit (as well as the 10th) has *rejected* the precise arguments that S&N is making here.

Approximately one year ago, S&N told this Court in its Status Report that “[t]he Federal Circuit’s decision vacating the judgment of infringement also vacates the damages award, as a matter of law.” Tamburo *Daubert* Resp Decl, Ex. 21, at 3. A week later, this Court specifically clarified with S&N whether the issue of damages would be part of a third trial, if one was necessary (that is, if the Court did not grant summary judgment on remand). S&N definitively responded: “Your Honor, that would be Smith & Nephew’s position. I think the Seventh Amendment would ***require*** that.” Tamburo *Daubert* Resp Decl, Ex. 22, at 20 [emphasis added]. Counsel for Arthrex agreed. *Id.*

With almost no legal analysis, S&N now switches over and incorrectly asserts that “[t]he law of the case doctrine and mandate rule preclude any re-litigation of these [damages] issues at trial.” S&N *Daubert* at 17. Neither doctrine supports S&N’s position.

Law of the case does not preclude litigation of damages issues. When the Federal Circuit reversed the judgment of liability on Arthrex’s appeal, *Smith & Nephew, Inc. v. Arthrex, Inc.*, No. 09-1091, 2009 U.S. App. LEXIS 26268 (Fed. Cir. Dec. 2, 2009), the corresponding remedies for that judgment, *i.e.*, the monetary damages and permanent injunction, were nullified. *Wheeler v. John Deere Co.*, 935 F.2d 1090, 1096 (10th Cir. 1991) (“Reversal of a judgment and remand for a new trial places the parties in the same position, insofar as relief is concerned, as if the case

had never been tried.”). As the Federal Circuit explained, the damages and injunction rulings, both of which are part and parcel of the infringement judgment, cannot stand because “a vacated judgment ‘has *no preclusive force* either as a matter of collateral or direct estoppel *or as a matter of the law of the case.*’” *United States Philips Corp. v. Sears Roebuck & Co.*, 55 F.3d 592, 598 (Fed. Cir. 1995) (quoting *No East-West Highway Committee, Inc. v. Chandler*, 767 F.2d 21, 24 (1st Cir. 1985) (emphasis added)); *see also Butler v. Eaton*, 141 U.S. 240, 244 (1891) (stating that the effect of reversal is that the judgment is “without any validity, force, or effect, and ought never to have existed”).

The mandate rule does not apply in this instance, quite simply because these issues were not presented to the Federal Circuit. As the Federal Circuit stated in the case cited by S&N, “[o]nly the issues actually decided -- those within the scope of the judgment appealed from, minus those explicitly reserved or remanded by the court -- are foreclosed from further consideration.” *Engel Indus., Inc. v. Lockformer Co.*, 166 F.3d 1379, 1383 (Fed. Cir. 1999). On remand, “a district court is free to take any action that is consistent with the appellate mandate.” *Exxon Chem. Patents v. Lubrizol Corp.*, 137 F.3d 1475, 1484 (Fed. Cir. 1998) (citing *United States v. Cote*, 51 F.3d 178, 182 (9th Cir. 1995)). None of the issues that S&N is seeking to preclude were actually decided or explicitly reserved by the Federal Circuit’s mandate.

S&N’s argument, that the Court must (or should) reinstate a damage award or finding when the underlying judgment is reversed on appeal, was explicitly *rejected* by the Ninth Circuit in *Local 159 v. Nor-Cal Plumbing, Inc.*, Nos. 96-16172 and -16284, 1999 U.S. App. LEXIS 17968, at *36-37 (9th Cir. July 27, 1999). In that case, the district court had granted summary judgment in plaintiff’s favor, and damages were awarded. The defendant appealed the grant of summary judgment, but not the compensatory damage award. *UA Local 343 of the United Ass’n*

of Journeymen & Apprentices of the Plumbing & Pipefitting Indus. v. Nor-Cal Plumbing, Inc., 48 F.3d 1465, 1469 (9th Cir. 1995). The trial on remand involved both liability and damages. The jury found for the plaintiff, but awarded less than the previous damage award. *Local 159*, 1999 U.S. App. LEXIS 17968, at *37. The plaintiff appealed the damages and argued, like S&N here, that the original damages award should have been reinstated, and that the district court erred by allowing the jury to decide damages anew. The Ninth Circuit *rejected* plaintiff's argument, explaining that the earlier reversal "necessarily nullified" the first damage award, and therefore, plaintiff had no right to reinstatement of damages from the earlier proceeding. *Id.* Without using the term, the Court's opinion also covered the mandate rule, explaining that there was no preclusion on the damage award because the previous appellate decision "did not decide the issue explicitly or by necessary implication." *Id.*

The Ninth Circuit's decision, which definitely rejects S&N's argument,¹¹ relied on the Tenth Circuit's opinion in *Wheeler v. John Deere Co.*, 935 F.2d 1090 (10th Cir. 1991). In *Wheeler*, just like here, the plaintiff won at the first trial, and the defendant appealed liability, but not damages. *Id.* at 1096. After liability was reversed on appeal, both liability and damages were retried. The plaintiff again won and was awarded damages, although less than at the first trial. *Id.* at 1093. The Tenth Circuit flatly rejected plaintiff's argument that the district court should have reinstated the damage award from the first trial. The Tenth Circuit held that it would be legal error to preclude relitigation of damages where a liability judgment is reversed, stating:

Once we reversed the original judgment incorporating the first jury's verdict and our mandate issued, the first verdict became null and void in

¹¹ *Lazare Kaplan Intern., Inc. v. Photoscribe Technologies, Inc.*, 628 F.3d 1359, 1366 (Fed. Cir. 2010) (stating that the law of the regional circuit is applied for "procedural issue[s] not unique to patent law").

its entirety. The district court could no more reinstate the damages portion of the first verdict than it could substitute the second jury's award with a larger sum pulled out of a magically appearing hat. *See Dr. Seuss, The 500 Hats of Bartholomew Cubbins* (1938).

Id. at 1096.¹²

Even if the law were not so clear, there are factual reasons why S&N's suggested preclusion is inappropriate. With respect to the testimony on lost profits before 2006, Arthrex addressed the requested exclusion of this evidence in response to S&N's Motion *in Limine* No. 54, explaining that Arthrex's damages expert will testify consistently with Arthrex's theory on lost profits throughout this case. Even under S&N's theory, lost profits is a live issue requiring consideration at this trial, there is no reasons to restrict the testimony.¹³

With respect to S&N's assertion that Mr. Paris should be precluded from testifying contrary to the statement in this Court's vacated Injunction Statement, Arthrex addressed the requested exclusion of this evidence in response to S&N's Motion *in Limine* No. 53. There, Arthrex explained that the fact findings underlying the vacated judgment were similarly vacated and could not serve as the basis of estoppel or waiver to preclude contrary testimony.

Finally, S&N argues that Arthrex's damages expert should not be permitted to testify on the appropriate royalty rate in the reasonable royalty calculation. As even S&N must concede,

¹² The scant legal authority that S&N cites does not change these definitive holdings. None (cited in this *Daubert* motion or its Trial Memorandum) are remotely like S&N's contention here, that a plaintiff is entitled to have its damages award reinstated where the underlying judgment was reversed on appeal.

S&N also makes a passing suggestion -- again without legal analysis or support -- that Arthrex waived its ability to challenge damages upon retrial. This too is incorrect. The Ninth Circuit also rejected this argument in *Local 159*, described above, holding that the defendant "did not concede the validity of the amount awarded on summary judgment by not appealing the amount of damages" when it appealed the original summary judgment decision. 1999 U.S. App. LEXIS 17968, at *37. S&N has not cited to a single authority to the contrary.

¹³ S&N's assertion that Arthrex did not challenge any of the lost profits testimony at the last trial is wrong, as we demonstrated in response to S&N's MIL 54. Arthrex Response at 27-30.

the law relating to the analysis of the appropriate reasonable royalty rate has recently changed significantly. In January of this year, the Federal Circuit ruled as a matter of law that the “25% rule of thumb” can no longer be applied in assessing the appropriate rate because the test “is a fundamentally flawed tool for determining a baseline royalty rate in a hypothetical negotiation... [that] fails to pass muster under *Daubert*.” *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, ___, 2011 WL 9738, at *19 (Fed. Cir. Jan. 4, 2011). In his testimony to the jury, Mr. Troxel relied on the 25% rule of thumb in supporting his opinion that a 16% royalty rate was appropriate, and he even called 25% a “conservative” apportionment of profits. Tamburo *Daubert* Resp Decl, Ex. 1, at 727.¹⁴ Just as the Federal Circuit held in *Uniloc*, Mr. Troxel’s “testimony was based on the use of the 25% rule of thumb as an arbitrary, general rule, unrelated to the facts of this case,” and as such Arthrex should be “entitled to a new trial on damages.” *Uniloc*, 2011 WL 9738, at *22.¹⁵

Uniloc represents a “change in the law” that should entitle Arthrex to retry the issue of the appropriate reasonable royalty rate. Even under the harshest application of law of the case or waiver doctrines (which, as explained above, cannot apply), courts recognize that a change in law represents a circumstance that would permit further litigation on an issue. *Daiichi*, at *6 (citing *Pub. Interest Research Group of N.J., Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111,

¹⁴ This change in law caused Mr. Troxel to change his approach in his recent expert report. Tamburo *Daubert* Resp Decl, Ex. 23, at 28-30 (discussing the relevant changes between Mr. Troxel’s 2006 and 2010 reports, including the elimination of the 25% rule for assessing the reasonable royalty rate).

¹⁵ There have been other, more subtle, changes in binding case law for assessing the reasonable royalty rate that further establish that, on the facts, the 16% rate cannot be established for this trial. In fact, S&N relies on at least two of these cases in another *Daubert* Motion to support exclusion of Arthrex’s expert’s testimony. S&N *Daubert* at 25-26. Specifically, S&N relies on both *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301 (Fed. Cir. 2010) and *ResQNet.Com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010) as “recently” setting forth the law regarding whether a license is sufficiently comparable to constitute proper evidence under the *Georgia-Pacific* analysis of the reasonable royalty rate.

116-17 (3d Cir. 1997) for the proposition that a circumstance that warrants a court's reconsideration of an issue occurs when "a supervening new law has just been announced"); *Forshey v. Principi*, 284 F.3d 1335, 1356 (Fed. Cir. 2002) (recognizing that waiver should not apply "when there is a change in the jurisprudence of the reviewing court or the Supreme Court after consideration of the case by the lower court"). The Ninth Circuit recognizes this general exception as well. *United States v. Matwyuk*, 184 Fed. Appx. 671, 672 (9th Cir. 2006) (recognizing "the intervening controlling authority exception to the mandate rule and the law of the case doctrine") (citing *U.S. v. Bad Marriage*, 439 F.3d 534, 538 (9th Cir. 2006)).

It is not only appropriate, but actually **required** by Ninth Circuit law, that the parties relitigate the appropriate damages. Should the Court disagree (and Arthrex vigorously contends that this Court should *not* adopt S&N's position), and believe that law of the case or some other doctrine precludes relitigation of the damages issues, then the entirety of the prior damage proceedings would need to be followed. This would include this Court's prior decision that S&N cannot obtain damages for the period of January 1, 2006 through June 2008. Tamburo *Daubert* Resp Decl, Ex. 24, at 34. For all the foregoing reasons, S&N's motion should be denied in its entirety.

Response to *Daubert* 11

In this Motion, S&N seeks to preclude Arthrex from presenting what it characterizes as new arguments regarding damages. As with its Motion *in Limine* No. 54, S&N assumes that Arthrex is bound by everything that happened before, and that Arthrex cannot change a thing. For many of the reasons set forth in Response to S&N's *Daubert* No. 10 and S&N's Motion *in Limine* No. 54, this motion is baseless and should be denied. That is, the damages determination was part and parcel of the original judgment, and when that judgment was vacated, so too was the jury's damage award. *Wheeler v. John Deere Co.*, 935 F.2d 1090, 1096 (10th Cir. 1991)

Exhibit 5

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With respect to S&N's proposed addition to the claim construction, this Court has already rejected S&N's request. This is the identical addition that S&N requested in its motion for summary judgment and which Arthrex opposed. Tamburo MIL Resp Decl, Ex. 23, at 3-4; Ex. 24, at 15, n.11. The court rejected S&N's request when it stated the construction it intends to give in its August 31, 2010 Order denying the parties' cross-motions for summary judgment. Tamburo MIL Resp Decl, Ex. 25, at 2.

Response to Motion 53

In this Motion, S&N asks the Court to preclude Arthrex from introducing evidence or argument contrary to the Court's [vacated] injunction findings. S&N gives no legal authority, it simply concludes that the statements in the injunction should be given conclusive effect because, in its view, "every single one of the Court's finding was untouched by the appeal." S&N MIL, at 30. S&N's conclusion runs afoul of the law.

S&N does not dispute that when the Federal Circuit reversed the judgment of liability following the second trial, the injunction which was premised on that judgment became a nullity. *Wheeler v. John Deere Co.*, 935 F.2d 1090, 1096 (10th Cir. 1991) ("Reversal of a judgment and remand for a new trial places the parties in the same position, insofar as relief is concerned, as if the case had never been tried"). As explained in Arthrex's MIL IX, the injunction therefore "has *no preclusive force* either as a matter of collateral or direct estoppel or as a matter of the law of the case.'" *United States Philips Corp. v. Sears Roebuck & Co.*, 55 F.3d 592, 598 (Fed.

motive appears to be yet another attempt to have this Court modify its construction of "Resile" and "Resilient" and include at the end of that construction S&N's desired phrase that "although other factors may supplement the lodging effect caused by resilience." S&N MIL, at 27. Just as it did during summary judgment, this Court should not entertain S&N's request to modify the claim construction. As Arthrex previously explained, to do so runs the risk of jury confusion between "causing" lodging and "supplementing" lodging. Should the Court agree to add S&N's language, then it should also add that "anchor resilience must be the sole cause of lodging" to minimize the risk of jury confusion that S&N attempts to create.

Cir. 1995) (quoting *No East-West Highway Committee, Inc. v. Chandler*, 767 F.2d 21, 24 (1st Cir. 1985)); *see also Butler v. Eaton*, 141 U.S. 240, 244 (1891) (stating that the effect of reversal is that the judgment is “without any validity, force, or effect, and ought never to have existed”). Despite this black letter law -- and a lack of any binding precedent to the contrary -- S&N expects that the assertions made in this Court’s Statement of Reasons in Support of the Injunction (“Injunction Statement,” Tamburo MIL Resp Decl, Ex. 26) should be taken as established for purposes of the upcoming trial. That is not proper.

S&N is incorrect to say that these findings remain law of the case. When the injunction is vacated, it follows that the findings of fact that this Court made to support the injunction are also vacated and have no preclusive effect. *Dodrill v. Ludt*, 764 F.2d 442, 444 (6th Cir. 1985). The U.S. Court of Appeals for the Sixth Circuit explained why this rule makes practical sense:

If a judgment could be entirely vacated yet preclusive effect still given to issues determined at trial but not specifically appealed, appellants generally would feel compelled to appeal every contrary factual determination. Such inefficiency neither lawyers nor judges ought to court. Litigants ought to be encouraged to expend their energies on their most compelling issues and arguments, without paranoia about the preclusive effect of other issues or determinations.

Id. at 444. The Federal Circuit has followed this approach, holding that factual findings cannot have preclusive effect where the underlying judgment is vacated. *Rumsfeld v. Freedom NY, Inc.*, 329 F.3d 1320, 1332 (Fed. Cir. 2003). In *Rumsfeld*, the appellant argued that the Board from which it appealed was bound by its own findings of fact in a related case, despite the fact that the related decision was vacated. The Federal Circuit disagreed, holding “the Board was free to come to different factual conclusions the second time around without revisiting its decision in the earlier vacated decision.” *Id.*

It is also incorrect to say that Arthrex waived or abandoned its ability to challenge the injunction. As an appellate court, the Federal Circuit reviews judgments, not opinions, and

Arthrex unquestionably challenged the relevant judgment. *See Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 317 (Fed. Cir. 1985) (“This court hears appeals from judgments, ***not from language used in justification of the judgment*** appealed from.”) (emphasis added).

Moreover, the same day that Arthrex filed its Notice of Appeal with the Federal Circuit, it filed an Emergency Motion to Stay the Injunction pending the appeal on the merits of the Judgment. Although the Injunction Statement had not issued at the time that Arthrex filed its Motion to Stay, in addition to the merits of the underlying judgment, Arthrex also addressed the public interest, irreparable harm and the balance of equities, all of the issues underlying this Court’s injunction statement. Tamburo MIL Resp Decl, Ex. 26. The Motion to Stay was granted, and subsequently, the judgment underlying the injunction was reversed. *Smith & Nephew, Inc. v. Arthrex, Inc.*, No. 09-1091, 2009 U.S. App. LEXIS 26268 (Fed. Cir. Dec. 2, 2009).

Finally, it is of no moment that “virtually all of these findings relate solely to damages issues.” S&N MIL, at 29. Even if S&N were accurate (and it is not),¹⁷ damages determinations, like other underlying fact-findings, necessarily lose effect when a judgment is vacated. As S&N itself told the Court a year ago, “[t]he Federal Circuit’s decision vacating the judgment of infringement also vacates the damages award, as a matter of law.” Tamburo MIL Resp Decl, Ex. 1, at 3. The Tenth Circuit colorfully characterized the same preclusion argument that S&N is attempting to make as magic, stating: “The district court could no more reinstate the damages portion of the first verdict than it could substitute the second jury’s award with a larger sum

¹⁷ More than one third of the Court’s statements either relate to or are specifically predicated on the jury’s finding of infringement, which has since been reversed. *See* Tamburo MIL Resp Decl, Ex. 26, at ¶¶ 1, 3, 4, 5, 7, 8, 16, 19, 20, 21, 24, 31, 32, 33, 34, 38, 40, 41, 44, 45, 47, 48, 49, 50, 51, 57, 61, 62, 63, 65, 70, 76, 77, 89, and 90.

pulled out of a magically appearing hat.” *Wheeler v. John Deere Co.*, 935 F.2d 1090, 1096 (10th Cir. 1991) (citing Dr. Seuss, *The 500 Hats of Bartholomew Cubbins* (1938)).

The Injunction Statement is necessarily intertwined with the judgment that was reversed, and the statements reported therein can have no preclusive effect in this case. For these and the additional reasons explained in Arthrex’s MIL IX, S&N’s MIL 53 should be denied.

Response to Motion 54

This motion seeks to limit Arthrex’s ability to present a complete defense with respect to the appropriate damages in this case on the ground that it is contrary to Arthrex’s “original” lost profits analyses. Without legal authority, S&N just assumes that Arthrex is bound by everything that happened before as it relates to lost profits, and Arthrex cannot change a thing. S&N is wrong both on the law and on the facts.

As explained in response to S&N’s MIL 53, and more fully in response to S&N’s *Daubert* 10, Arthrex’s challenge to S&N’s damages analysis is entirely appropriate. The damages verdict disappeared when the judgment was reversed. *Wheeler v. John Deere Co.*, 935 F.2d 1090, 1096 (10th Cir. 1991) (“Reversal of a judgment and remand for a new trial places the parties in the same position, insofar as relief is concerned, as if the case had never been tried”). And the Ninth Circuit has held that a plaintiff has no right to have a damage determination reinstated after the underlying judgment is reversed. *Local 159 v. Nor-Cal Plumbing, Inc.*, No. 96-16172, 1999 U.S. App. LEXIS 17968, at *36-37 (9th Cir. July 27, 1999).

Moreover, both parties anticipated that damages issues would be retried if a third trial was held. S&N itself told this Court a year ago that the reversal of the judgment vacated the damage award as a matter of law. *See supra* at 3. S&N also told this Court that the Seventh Amendment gave the parties a right to a new trial on damages, and Arthrex agreed. Tamburo MIL Resp Decl, Ex. 2, at 20.

Exhibit 6

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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

**SMITH & NEPHEW, INC, and JOHN
O. HAYHURST, M.D.,**

Plaintiffs,

v.

ARTHREX, INC.,

Defendant.

Case No. CV08-0714 MO

**MEMORANDUM IN SUPPORT OF
DEFENDANT'S MOTIONS IN
LIMINE**

ORAL ARGUMENT REQUESTED

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patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analysis.”).

S&N cannot excuse its judicial admission because it tried to qualify its assertion by adding the phrase “appears to be” to its assertion about Judge Hubel’s finding. That is nothing more than clever gamesmanship, certainly not the type of conduct that should be rewarded. Similarly, S&N cannot avoid this sanction by contending “I didn’t really mean it; Judge Hubel’s statement really didn’t go that far.” If anything, such a contention would make S&N’s conduct even worse. It would show this was no honest mistake; this was a calculated move to lead the Federal Circuit to the very conclusion it reached.²⁰ Such conduct simply should not be countenanced.

For all the foregoing reasons, Arthrex asks that S&N be precluded from acting inconsistently with its position before the Federal Circuit, and that the jury be told that lodging through an interference fit is “expressly excluded” from the coverage of the ‘557 patent.

MOTION IN LIMINE IX: S&N SHOULD BE PRECLUDED FROM USING THE COURT’S STATEMENT FOR REASONS SUPPORTING [ITS VACATED] PERMANENT INJUNCTION IN JURY INSTRUCTIONS OR WITH ITS WITNESSES

As the Court knows, the judgment from the second trial, and with it the resulting injunction, was reversed by the Federal Circuit. Nevertheless, S&N wants the Court to read to the jury (as part of the jury instructions) many of the statements contained in the Court’s Statement for Reasons Supporting Permanent Injunction (“Injunction Statement”) as established

²⁰ When a “party making an ostensible judicial admission explains the error in a subsequent pleading or by amendment, the trial court must accord the explanation due weight,” *Sicor Ltd. v. Cetus Corp.*, 51 F.3d 848, 859-860 (9th Cir. 1995). S&N has presented no such explanation here. Rather, S&N allowed the Federal Circuit to rely on its statement, and has since allowed the statement to go uncorrected for nearly two years. If S&N plans to present evidence or argument contrary to its earlier statement, such litigation-inspired tactics should not be permitted and any such evidence should be excluded.

facts. *See* Tamburo Decl., Ex. 30 at 8, 51, 56-57, 68, 71-74. Moreover, the report of its damages expert, Mr. Troxel, is replete with references to the Injunction Statement in support of his opinion. While we do not know for sure, it appears that Mr. Troxel (and perhaps other witnesses) are planning to refer to the Injunction Statement at trial. All of this is improper, as explained below, and should not be permitted.

After the second trial in 2008, this Court orally granted S&N's Motion for a Permanent Injunction (Tamburo Decl., Ex. 32 (describing Minutes of Proceeding)), and the injunction became part of the judgment. Subsequently, the Court issued the Injunction Statement explaining the reasons for entering the injunction. Almost all of assertions in the Injunction Statement either involved disputed issues at trial or were conclusions without record support.

In December 2008, Arthrex filed its Notice of Appeal and the same day, asked the Federal Circuit to stay the injunction. Thereafter, on January 14, 2009, the Court of Appeals for the Federal Circuit issued an Order, staying the injunction pending the appeal. Tamburo Decl., Ex. 33. After full briefing and argument on the appeal, the Federal Circuit modified this Court's claim construction and reversed the judgment and remanded for a new trial on infringement. *Smith & Nephew, Inc. v. Arthrex, Inc.*, 2009-1091, 2009 U.S. App. LEXIS 26268 (Fed. Cir. Dec. 2, 2009). It should go without saying that the reversal of the judgment made the injunction a nullity that no longer is in effect.

Despite the fact that the reversal of the underlying judgment means that the injunction is not in effect, it appears that S&N expects that the assertions made in this Court's Injunction Statement should be taken as established for purposes of this new trial. That is not proper for several reasons.

First, the Injunction Statement is not entitled to preclusive effect because the underlying judgment was reversed. *Smith & Nephew, Inc. v. Arthrex, Inc.*, 2009-1091, 2009 U.S. App. LEXIS 26268 (Fed. Cir. Dec. 2, 2009). It is black letter law that “a vacated judgment ‘has *no preclusive force* either as a matter of collateral or direct estoppel or as a matter of the law of the case.’” *United States Philips Corp. v. Sears Roebuck & Co.*, 55 F.3d 592, 598 (Fed. Cir. 1995) (quoting *No East-West Highway Committee, Inc. v. Chandler*, 767 F.2d 21, 24 (1st Cir. 1985)) (emphasis added); 18 James W. Moore, *Moore Moore's Federal Practice*, ¶131.30[2][c][iii] (3d ed. 1997). The Ninth Circuit follows this rule. *Ornellas v. Oakley*, 618 F.2d 1351, 1356 (9th Cir. 1980) (“A reversed or dismissed judgment cannot serve as the basis for a disposition on the ground of res judicata or collateral estoppel.”). Moreover, the fact-findings that relate to a reversed judgment similarly have no estoppel effect because “[t]he reversal...vacates the judgment entirely, technically leaving nothing to which [a court] may accord preclusive effect.” *Dodrill v. Ludt*, 764 F.2d 442, 444 (6th Cir. 1985). This is true regardless of whether the fact-findings were specifically challenged on appeal or whether the judgment was vacated on some other ground. *Id.*

Second, presenting assertions from the Injunction Statement as matters of established fact, as S&N intends to do, should not be allowed under Fed. R. Evid. 403 because it would mislead the jury and unfairly prejudice Arthrex. *See Mendenhall v. Cedarapids*, 5 F.3d 1557, 1573 (Fed. Cir. 1993) (stating “evidence [regarding prior litigation] must pass muster, like any other evidence, as relevant and probative of an issue in the second case . . . and nevertheless, be excluded under Rule 403 if its probative value is substantially outweighed by its prejudice to one’s adversary or because of the likelihood of confusion of the jury”). In particular, presentation of the assertions in this Court’s Injunction Statement “presents the danger that a jury

may give the judicial opinion undue weight or be confused, believing the earlier court's findings somehow binding on it." *Johnson v. Colt Indus Operating Corp.*, 797 F.2d 1530, 1534 (10th Cir. 1986). Moreover, presenting findings from the earlier litigation would unfairly prejudice Arthrex because the earlier case involved an infringement inquiry based on a claim construction that was held to be incorrect, and which was subsequently modified in Arthrex's favor. *See St. Clair Intellectual Prop. Consultants v. Fuji Photo Film Co., Ltd.*, 674 F. Supp. 2d 555, 559 (D. Del. 2009) (excluding evidence of prior patent litigation results because "any probative value of the prior verdict was substantially outweighed by the potential for undue prejudice [to the defendant]").

Similarly, Mr. Troxel, S&N's damages expert (or any other witness), should not be able to present any opinion or conclusion that is based solely on the Injunction Statement. Although an expert can, in certain circumstances, rely on inadmissible evidence, the Injunction Statement, which consists of conclusions from an overturned judgment, is not the type of information "reasonably relied upon by experts." Fed. R. Evid. 703; *see Turner v. Burlington Northern Santa Fe R.R.*, 338 F.3d 1058, 1062 (9th Cir. 2003) (affirming the district court's decision to exclude an expert from testifying where an inadmissible lab report was the only "substantive evidence of his ultimate conclusions").

This works no prejudice to Mr. Troxel or S&N. He is free to rely upon existing facts underlying any assertion in the Injunction Statement, assuming, of course, that the underlying evidence appropriately supports his opinion. That is the way all experts testify, and Mr. Troxel should be no different.

In its Trial Memorandum, S&N states that "Arthrex *abandoned* any challenge to the injunction itself or to any of the Court's findings relating to it." *See Tamburo Decl.*, Ex. 31 at 5.

Any such argument, should it be made, is wholly without merit. First, as shown above, S&N's contention that there is any estoppel or "law of the case" with respect to the Injunction has no credibility because the judgment underlying the injunction was reversed. Second, Arthrex did challenge the injunction, first by seeking an emergency stay of the injunction pending a resolution of the merits of the appeal of the judgment (which was granted), and second, by challenging the judgment of infringement in favor of S&N (which was reversed). Accordingly, Arthrex did not abandon its challenge to the injunction, but rather, it successfully challenged the underlying judgment, the result of which served to end the injunction entered by the Court.

MOTION IN LIMINE X: S&N'S FACT WITNESS, JOHN MAHONEY, SHOULD BE PRECLUDED FROM TESTIFYING BEYOND HIS TESTIMONY AT THE 2008 TRIAL AND BEYOND THE TESTIMONY OF HIS PREDECESSOR, MR. MAY, AT THE 2007 TRIAL

Prior to the last trial, S&N informed Arthrex that Thomas May, S&N's former Director of Marketing, was replaced by John Mahoney. S&N submitted a witness narrative for Mr. Mahoney and Arthrex objected to his testimony and requested that instead of introducing a new witness at that time, Mr. May's deposition be read to the jury. Tamburo Decl., Ex. 34 at 7-8. In the alternative, Arthrex requested that it be able to depose Mr. Mahoney prior to trial since it had not previously taken his deposition.

The Court refused Arthrex's request to depose Mr. Mahoney and instead agreed to allow his testimony on two conditions, i) that S&N satisfy the Court that Mr. May has been asked to testify and is unwilling; and ii) that Mr. Mahoney cannot add topic areas to what Mr. May testified to at the first trial. Tamburo Decl., Ex. 3 at 17-18.

Mr. Mahoney did testify at the 2008 trial, and S&N followed the Court's directive and limited Mr. Mahoney's testimony to the topics covered by Mr. May at the 2007 trial. For this trial, however, S&N apparently believes it is free to ignore the court's prior ruling. According to

Dated: May 2, 2011

By: /s/ Charles W. Saber

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Exhibit 7

**UNITED STATES DISTRICT COURT
DISTRICT OF OREGON**

AMENDED CIVIL MINUTES

Case No.: CV 04-29-MO

Date of Proceeding: May 17, 2011

Case Title: Smith & Nephew v. Arthrex

Presiding Judge: Hon. Michael W. Mosman

Courtroom Deputy: Dawn Stephens

Reporter: Bonita Shumway

Tape No: _____

DOCKET ENTRY: RECORD OF PRETRIAL CONFERENCE

MOTIONS IN LIMINE

Order GRANTING IN PART / DENYING IN PART Plaintiffs' Motion in Limine [811, 813] as follows:

38. GRANTED IN PART / DENIED IN PART. The parties are not to litigate whether surgeons are direct infringers, double patenting, or validity. The parties may litigate liability and damages, including royalty rates and sales.
39. GRANTED. Preferred embodiments are not to be introduced.
40. GRANTED. Comparison to any product or group of products to Arthrex anchors are not allowed.
41. GRANTED IN PART / DENIED IN PART as further explained in discussion of plaintiffs' Motion in Limine 42. The parties are not required to test whether the patent works.
42. GRANTED IN PART / DENIED IN PART. Dr. Goble may not compare products that lodge by resilience with Arthrex's anchors. He may compare Arthrex's anchors only to the description in the patent. He may discuss features that aid or inhibit lodging by resilience.
43. GRANTED as to 677 and 678. GRANTED as to 660 as currently redacted. Arthrex may attempt to resubmit following further redaction.
44. GRANTED IN PART / DENIED IN PART. Non-inventor witness may not offer expert testimony. Inventors may not reference tests, studies, or scientific data. They may speak in general terms.
45. GRANTED, as discussed above.
46. GRANTED IN PART / DENIED IN PART, as discussed above.
47. GRANTED. Arthrex may not argue validity.
48. GRANTED IN PART. Redundant material will be excluded.
49. GRANTED IN PART / DENIED IN PART. Experts may expound articles, studies, reports, theories and data previously addressed in their reports. They may not introduce articles, studies, reports, theories or data that were not included in their reports.
50. GRANTED. Witness testimony is limited to their witness statements.
51. GRANTED. Evidence that is inconsistent with Daubert rulings is excluded.

52. DENIED. The parties may argue about the definition of “sufficiency.”
53. DENIED. The findings of the permanent injunction are no longer in effect. The parties may not introduce these findings.
54. DENIED. The parties may argue damages.
55. DENIED, in accordance with prior rulings.
56. GRANTED. Mr. O’Connor’s testimony cannot include comments that are not based on current claim construction.
57. GRANTED. Previous trials may not be discussed. The parties may litigate willfulness.

Order GRANTING IN PART/DENYING IN PART Defendants’ Motion in Limine [802] as follows:

1. DENIED. Willfulness will be determined by the jury.
2. DENIED. Dr. Hayes did not spoil evidence.
3. DENIED. Parties may discuss the laws of physics.
4. DENIED. Parties may discuss engineering resilience.
5. GRANTED IN PART / DENIED IN PART. The parties may not criticize the failure to follow the procedure in Exhibit Q, but may otherwise criticize the test.
6. GRANTED IN PART / DENIED IN PART. Dr. Hayes may discuss the results from stationary weights, but may not introduce results from the dropping experiments. He may explain that dropping the weight increases the force.
7. DENIED. Comparisons are allowed only for damages.
8. DENIED.
9. GRANTED. The findings of the permanent injunction are no longer in effect.
10. DENIED. The parties may discuss damages.

DAUBERT MOTIONS

Order GRANTING IN PART / DENYING IN PART Plaintiffs’ Daubert Motions [799] as follows:

6. GRANTED. Evidence of failure during rehabilitation is excluded.
7. GRANTED IN PART / DENIED IN PART.
 - a. The surgical tug is not a necessary step in lodging, but it may be evidence of whether lodging has previously occurred.
 - b. If cited in his report, Dr. Greenleaf may discuss the test he performed and its result, but may not extrapolate this result based on his experience.
8. GRANTED IN PART / DENIED IN PART. Parties may show that forces applied to the anchor during the tests shows its unsuitability to attach tissue to bone.
9. GRANTED IN PART / DENIED IN PART as described above.
10. DENIED. The parties may litigate damages, including royalty rates and lost profits.
11. DENIED. Prior party admissions may be used on cross-examination.
12. DENIED. Arthrex will provide opposing counsel with an unredacted copy of the redacted portion.
13. DENIED. Not all foam block testing is excluded.

Order GRANTING IN PART / DENYING IN PART Defendants’ Daubert Motions [806] as follows:

1. DENIED.
2. DENIED. The parties may argue the definition of sufficiency and the normal forces of surgery.

EXHIBITS

Plaintiffs' Exhibits

- 26. Objection withdrawn. Admitted.
- 27. Admitted.
- 30. Admitted.
- 54. Redactions to be made. Admitted upon redaction.
- 66. Parts L and M are withdrawn. The remainder of 66 is admitted.
- 99. Objection withdrawn. Admitted.
- 112. Exhibit withdrawn with leave to resubmit.
- 114. Objection withdrawn. Admitted.
- 118. Objection withdrawn. Admitted.
- 134. Objection withdrawn. Admitted.
- 136. Objection withdrawn. Admitted.
- 137. Objection withdrawn. Admitted.
- 138. Objection withdrawn. Admitted.
- 139. Objection withdrawn. Admitted.
- 152. Objection withdrawn. Admitted.
- 166. Redactions to be made. Admitted upon redaction.
- 167. Redactions to be made. Admitted upon redaction.
- 168. Redactions to be made. Admitted upon redaction.
- 172. First two pages are not admitted but may become demonstrative exhibits. The remainder is admitted, following redaction. Arthrex will be free to admit any unused portions of Dr. Tencer's report as a new defense exhibit.
- 178. Admitted upon replacement.
- 179. Objection withdrawn. Admitted.
- 242. Exhibit withdrawn.
- 244–47, 250–51. Objections sustained. These exhibits are not admitted. Parties may argue about the use of the line measurement method.
- 260. Objection withdrawn. Admitted.
- 261. Objection withdrawn. Admitted.
- 354. Objection withdrawn. Admitted.
- 391. Withdrawn with leave to resubmit.
- 393. Withdrawn with leave to resubmit.
- 407. Objection withdrawn. Admitted.

- 414. Objected to portions are withdrawn.
- 415. Objected to portions are withdrawn.
- 442. Exhibit withdrawn.
- 449. Withdrawn with leave to resubmit if used by expert report on damages.
- 451. Objection withdrawn. Admitted.
- 452. Objection withdrawn. Admitted.
- 453. Objection withdrawn. Admitted.
- 459. Redactions to be made. Admitted upon redaction.
- 462. Figure 5 is excluded. Figures 11 and 12 are withdrawn.
- 472. Objection withdrawn. Admitted.

All other exhibits are admitted.

Defendant's Exhibits

- 501. Admitted.
- 502. Exhibit withdrawn.
- 503. Not admitted.
- 504. Exhibit withdrawn.
- 505. Not admitted.
- 506. Not admitted.
- 507. Exhibit withdrawn.
- 508. Not admitted.
- 509. Exhibit withdrawn.
- 510. Not admitted.
- 511. Not admitted.
- 512. Not admitted.
- 513. Exhibit withdrawn.
- 514. Exhibit withdrawn.
- 515. Exhibit withdrawn.
- 516. Exhibit withdrawn.
- 517. Exhibit withdrawn.
- 518. Not admitted.
- 607. Exhibit withdrawn.
- 608. Exhibit withdrawn.
- 611. Exhibit withdrawn.

- 612. Admitted.
- 613. Exhibit withdrawn.
- 615. Objection withdrawn. Admitted.
- 616. Objection withdrawn. Admitted.
- 617. Exhibit withdrawn.
- 618-25. Admitted.
- 626. Exhibit withdrawn.
- 635. Exhibit withdrawn.
- 640. Exhibit withdrawn.
- 643. Exhibit withdrawn.
- 647. Exhibit withdrawn.
- 657. Exhibit withdrawn.
- 658. Exhibit withdrawn.
- 659. Exhibit withdrawn.
- 660. Not admitted, with leave to resubmit.
- 661. Exhibit withdrawn.
- 662. Exhibit withdrawn.
- 668. Exhibit withdrawn.
- 669–674. Admitted upon redaction.
- 675. Exhibit withdrawn.
- 676. Exhibit withdrawn.
- 677–79. Exhibits withdrawn.
- 684. Admitted.
- 685. Exhibit withdrawn.
- 699. Objection withdrawn as to first three pages; these are admitted. Final two pages are withdrawn.
- 700–01. Excluded.
- 708. Exhibit withdrawn.
- 713. Exhibit withdrawn.
- 754. Exhibit withdrawn with leave to resubmit.
- 756. Portions .01–.02 of the exhibit are withdrawn. Remainder taken under advisement at conference. Not admitted.
- 793. Exhibit withdrawn.
- 794. Exhibit withdrawn.
- 847. Excluded.

- 848. Exhibit withdrawn.
- 851. Exhibit withdrawn.
- 852. Exhibit withdrawn.
- 856. Exhibit withdrawn.
- 857. Exhibit withdrawn.
- 859. Exhibit withdrawn.
- 860. Exhibit withdrawn.
- 861. Exhibit withdrawn.
- 863. Exhibit withdrawn, but may be used as a demonstrative.
- 864. Taken under advisement at conference. Admitted.
- 893. Taken under advisement at conference. Admitted.
- 898. Taken under advisement at conference. Admitted.

All other exhibits are admitted.

ADDITIONAL MATTERS

The parties are to create new exhibit lists, including a rebuttal exhibit list, to provide to the opposing parties and the court.

The parties are to submit revised objections to deposition designations, revised objections to rebuttal exhibits and joint proposed jury instructions.

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Mark J. Hebert

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Anthony Philip Cho
Charles W. Saber
Peter E. Heuser
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cc: { } All counsel

DOCUMENT NO: _____

Exhibit 8

<p>1 IN THE UNITED STATES DISTRICT COURT 2 FOR THE DISTRICT OF OREGON 3 SMITH & NEPHEW, INCORPORATED,) and JOHN O. HAYHURST, M.D.,) 4) Plaintiffs,) No. CV-04-29-MO 5) vs.) 6) ARTHREX, INCORPORATED,) May 17, 2011 7) Defendant.) Portland, Oregon 8 _____) 9 10 11 12 13 Pretrial Conference 14 TRANSCRIPT OF PROCEEDINGS 15 BEFORE THE HONORABLE MICHAEL W. MOSMAN 16 UNITED STATES DISTRICT COURT JUDGE 17 18 19 20 21 22 23 24 25</p>	<p>1 (P R O C E E D I N G S) 2 THE CLERK: Your Honor, this is the time and place 3 set for a pretrial conference in Case No. 04-29-MO, Smith & 4 Nephew, Incorporated, et al. v. Arthrex, Incorporated. 5 Counsel, can you introduce yourself for the 6 record. 7 MR. SKENYON: John Skenyon of Fish & Richardson 8 for the plaintiffs. 9 MR. HEBERT: Mark Hebert, also of Fish & 10 Richardson for the plaintiffs. 11 MS. LEGAARD: Brenna Legaard from Chernoff 12 Vilhauer for plaintiffs. 13 MR. SABER: John Saber from Dickstein Shapiro for 14 Defendant Arthrex. 15 MR. TAMBURIO: Sal Tamburo from Dickstein Shapiro 16 for Defendant Arthrex. 17 MR. HEUSER: Peter Heuser with Schwabe Williamson 18 & Wyatt for Arthrex. 19 MR. CHO: Anthony Cho with Carlson Gaskey & Olds 20 for Arthrex. 21 MR. SCHMIEDING: Mr. John Schmieding. I'm general 22 counsel for Arthrex. 23 THE COURT: Welcome all of you to Portland. 24 Patents, the sport of kings. Here we are. 25 Let me make some introductions. You remember</p>
<p>1 APPEARANCES 2 3 FOR THE PLAINTIFFS: Mr. John M. Skenyon Mr. Mark J. Hebert 4 Fish & Richardson, PC 225 Franklin Street 5 Boston, MA 02110-2804 6 7 Ms. Brenna Legaard Chernoff Vilhauer McClung & 8 Stenzel, LLP 601 S.W. Second Avenue, Suite 1600 9 Portland, OR 97204 10 11 FOR THE DEFENDANT: Mr. Charles W. Saber Mr. Salvatore P. Tamburo 12 Dickstein Shapiro LLP 1825 Eye Street, NW 13 Washington, DC 20006 14 15 Mr. Anthony P. Cho Carlson, Gaskey & Olds, PC 16 400 W. Maple, Suite 350 Birmingham, Michigan 48009 17 18 Mr. Peter E. Heuser Schwabe Williamson & Wyatt 19 1211 S.W. Fifth Avenue, Suite 1900 Portland, OR 97204 20 21 COURT REPORTER: Bonita J. Shumway, CSR, RMR, CRR United States District Courthouse 22 1000 S.W. Third Ave., Room 301 Portland, OR 97204 23 (503) 326-8188 24 25 ALSO PRESENT: Mr. John Schmieding</p>	<p>1 Bonita Shumway, who was here for our last trial, and 2 fortunately I've been able to retain her for this trial. 3 Just to my left here is Joe Mueller, and over here 4 to my right is Paul Weitzel, my two law clerks this year. I 5 also have the good fortune of having Josh Smith here, who 6 clerks for Judge Redden, and having just finished a major 7 hearing in the salmon case, thinks he has a little spare 8 time. So he's helping us out somewhat here. 9 And the inimitable Dawn Stephens, in the center 10 here, to help you out with exhibits and the like. 11 So welcome to Portland for Dickstein Shapiro. 12 MR. SABER: Thank you, Your Honor. 13 MR. TAMBURIO: Thank you. 14 THE COURT: The weather is like this all the time. 15 It will be that way in June. 16 It's never fun to try a case a third time. I just 17 want to assure you that although I've made some private 18 complaints in chambers about the prospect of a third trial, 19 we'll give it our level best. Everybody on this team will 20 do our best to give you the best trial that we can. 21 Mr. Heuser, your name is on the briefing in this 22 case. So you had a hand in putting together the briefing 23 here? 24 MR. HEUSER: Yes, Your Honor. 25 THE COURT: And do you know these folks? You know</p>

<p style="text-align: right;">9</p> <p>1 could give a partial list. I was deeply saddened by my own 2 response, which was, "I don't know which of these two sides 3 I can trust. One says it's incomplete, one says it's '08 4 trial. In light of the briefing I received, I don't know 5 who to believe. I don't know who I can take to the bank." 6 So you need to stop. 7 This trial, you know, a ton of money involved. 8 Attorney's fees are going to be astronomical. But it 9 isn't -- trust me, I've had trials I wanted to win more than 10 anything. It isn't worth your reputation, and your 11 reputation has already been tarnished in my eyes before 12 we've even finished the pretrial conference. 13 So work with each other. We have a whole -- I 14 guess I thought that as we changed one of the variables in 15 the whole approach, we'd change the whole trial. I'm 16 disappointed to see that we've pretty much picked up where 17 we left off. Where we left off is not a good place to try a 18 case. It wouldn't make the public proud. So let's not do 19 it again. 20 I'm going to turn to the motions in limine first. 21 We'll go through those first and then the Daubert motions. 22 I've read carefully your trial memorandums and the 23 briefing on the motions in limine, and I'm not going to ask 24 for oral argument on very many of them -- some. I hope you 25 won't take that as any disrespect from me about why you're</p>	<p style="text-align: right;">11</p> <p>1 or not, and therefore whether Arthrex would be an indirect 2 infringer, if there is infringement. But otherwise, the 3 issue of resilience is pretty wide open, and that's the 4 whole case. It is honed in to that degree -- we've 5 eliminated validity questions and other issues -- but it is 6 pretty wide open on resilience. 7 The second is damages. And I understand Smith & 8 Nephew's argument on law of the case and law of the mandate. 9 I disagree that the damages issue can be -- that I have any 10 authority to narrow damages issues as much as Smith & Nephew 11 suggest. 12 And my own view is that the damages issue is 13 something to be tried all over again. So I'm not going to 14 impose a 16 percent royalty rate if they find infringement. 15 I'm not going to impose a certain number of previous sales 16 damages if they find infringement or the like. 17 So in the way in which it's phrased, I grant 38 in 18 part and deny it in part. The denial goes principally to 19 the way motion 38 frames the damages issue. I pretty much 20 grant 38 as to the infringement issue. 21 39 is to preclude Arthrex from making any further 22 references to the preferred embodiment. Here we come to the 23 first of several occasions that this comes up and Dr. Goble 24 comes up. So I think I'll save a more complete discussion 25 of Dr. Goble to motion 42, when it comes up.</p>
<p style="text-align: right;">10</p> <p>1 here or that you've made an effort to come here. Separate 2 from the complaint I just raised about your briefing, I 3 thought substantively you did a fine job of telling what the 4 issues were. 5 There are a couple of large issues that run 6 through many of these motions that I feel like I've resolved 7 in my own mind. So I hope you won't be surprised that we 8 don't belabor each one. If we did, we wouldn't have time to 9 do much else here today. 10 So let's start with plaintiffs' motions in limine. 11 And it will take me a minute to sort of peel back and forth 12 between the memorandum from plaintiffs and the response. 13 I'll start with the first one, which is No. 38. 14 And No. 38 is, again, one of those sort of overarching ones, 15 limit all evidence and argument in the third trial to the 16 only two issues that remain in dispute. And the two issues 17 that remain in dispute is whether the accused anchors 18 resiled in a manner sufficient to cause lodging with the 19 member in the hole; and the second is damages. 20 I think both sides agree at some general statement 21 of the issues that that's true. And I grant the motion to 22 that degree. So that means what I think is obvious, that 23 we're not going to have any validity issues, we're not going 24 to litigate double patenting or other such things. We're 25 not going to litigate whether surgeons are direct infringers</p>	<p style="text-align: right;">12</p> <p>1 39 is simply a motion that, taken at face value, 2 requires Arthrex not to compare Arthrex's accused devices to 3 any preferred or commercial embodiment. And I grant that 4 motion. I don't think Arthrex even disagrees with that 5 concept. 6 MR. SABER: No, we don't, Your Honor. 7 THE COURT: I grant that motion. 8 40: Preclude reference to expansion-fitted 9 automatic deployment or wings that expand. And Arthrex's 10 response again sort of gets at Goble and the planned 11 testimony there. 12 I'll take up the question of expansion fit when we 13 discuss 42, and automatic deployment also comes up in 42. I 14 don't know why we have to talk about wings that expand 15 unless you can help me with why any witness needs to bring 16 up a concept of wings that expand. 17 Is that part of Goble's testimony in any way? 18 MR. SABER: Well, Your Honor, the furthest that 19 Dr. Goble gets on something like that is as he explains the 20 various design concepts from his history, not particularly 21 talking about the preferred embodiment or anything like 22 that. He talks about how this kind of device would have -- 23 might have wings. That's just an example. 24 THE COURT: All right. Then I'm going to treat -- 25 I'm going to treat 40, which we're on, as completely covered</p>

<p style="text-align: right;">57</p> <p>1 So Smith & Nephew will try a case, arguing to the</p> <p>2 jury that other factors can supplement the lodging, Arthrex</p> <p>3 will try a case saying it's got to be the sole cause of</p> <p>4 lodging, and the jury will decide what they think about it.</p> <p>5 So I deny 52.</p> <p>6 53: Preclude Arthrex from introducing any</p> <p>7 evidence or argument contrary to the Court's permanent</p> <p>8 injunction findings.</p> <p>9 I view those findings as having been erased by the</p> <p>10 Federal Circuit's opinion, so they are free to do that. In</p> <p>11 fact, I might as well say that I grant Arthrex's</p> <p>12 doppelganger, to the degree that it prohibits Smith & Nephew</p> <p>13 or its witnesses from relying on those findings in the</p> <p>14 statement, since I view them as having been erased.</p> <p>15 54: Preclude Arthrex from introducing any</p> <p>16 evidence contrary to its original response on the lost</p> <p>17 profits claim.</p> <p>18 And I deny that. I'm going to throw damages wide</p> <p>19 open.</p> <p>20 55: Prohibit any evidence or argument regarding</p> <p>21 Moalli's work on the chapter of a manual on scientific</p> <p>22 evidence published by the FJC sent to every judge, stuck on</p> <p>23 every judge's shelf with all the other FJC monographs, never</p> <p>24 looked at again.</p> <p>25 That would normally come out, except Arthrex says,</p>	<p style="text-align: right;">59</p> <p>1 THE COURT: So he'll just use the data from</p> <p>2 Tencer's test?</p> <p>3 MR. SKENYON: And we've used it before, the</p> <p>4 testimony which we've designated from Dr. Tencer relating to</p> <p>5 that.</p> <p>6 THE COURT: That's fine.</p> <p>7 57: Preclude any reference to previous trials.</p> <p>8 And Arthrex says that's fine, creates problems for</p> <p>9 us on the willfulness. Both sides have moved on willfulness</p> <p>10 also.</p> <p>11 I deny Smith & Nephew's -- I think I already have</p> <p>12 denied Smith & Nephew's request to simply find willfulness</p> <p>13 here.</p> <p>14 Arthrex asks me not by way of summary judgment but</p> <p>15 by way of its own motion in limine -- which I'm about to get</p> <p>16 to -- to eliminate willfulness from the case.</p> <p>17 I'm sorely tempted to do so, since given the</p> <p>18 history of this case, I think Arthrex has a very strong</p> <p>19 argument for such. I'm not going to do so, and I'm not</p> <p>20 going to allow reference to prior trials, even though it</p> <p>21 does prejudice Arthrex somewhat in defending against</p> <p>22 willfulness, since I intend to take a second look at the</p> <p>23 willfulness issue post-trial if necessary.</p> <p>24 Let me be candid. I don't think this is</p> <p>25 illegitimate of me to say that one of my goals is to</p>
<p style="text-align: right;">58</p> <p>1 "Well, we had testimony about it earlier." And so given</p> <p>2 that we did have testimony about it earlier, as quoted, I'll</p> <p>3 allow it. In other words, I deny 55.</p> <p>4 56: Preclude Mr. O'Connor's testimony not based</p> <p>5 on current claim construction.</p> <p>6 And Arthrex's response is he's not an expert, so</p> <p>7 to the extent there are any words used in the claim in his</p> <p>8 testimony, he's not providing any opinions regarding those</p> <p>9 words or testimony relating to infringement opinions.</p> <p>10 That's a good case for 403 application if I ever</p> <p>11 heard it. So I grant 56. Mr. O'Connor's testimony cannot</p> <p>12 include concepts not based on current claim construction.</p> <p>13 Arthrex's response also -- again, skipping over</p> <p>14 the pejorative language -- suggests that its esteemed</p> <p>15 colleagues, Smith & Nephew, rely on the testimony of</p> <p>16 Dr. Allen Tencer, which is also based on -- only on now void</p> <p>17 claim construction.</p> <p>18 What's your response to that?</p> <p>19 MR. SKENYON: It's not. What we relied on was not</p> <p>20 anything Dr. Tencer said about claim construction lodging,</p> <p>21 but rather his test results, a comparison push-out test that</p> <p>22 both sides have done the same way in a variety of different</p> <p>23 formats.</p> <p>24 THE COURT: How will that come in in trial?</p> <p>25 MR. SKENYON: Through Dr. Hayes.</p>	<p style="text-align: right;">60</p> <p>1 engineer this trial so that we don't have a fourth trial,</p> <p>2 and if I grant your motion on willfulness and I'm wrong,</p> <p>3 then we have to have a fourth trial. If I grant your motion</p> <p>4 -- if I deny your motion on willfulness and the jury rules</p> <p>5 that I'm wrong, then we don't have to have a fourth trial.</p> <p>6 But don't lose much sleep over it, since I think</p> <p>7 you're probably right.</p> <p>8 That's plaintiffs' motions in limine.</p> <p>9 All right. Let's turn to defendant's motions in</p> <p>10 limine.</p> <p>11 I've ruled on No. 1, denied.</p> <p>12 No. 2, the spoliation of evidence argument. The</p> <p>13 parties have presented different sort of factual scenarios</p> <p>14 about what happened. And so I think I know what happened,</p> <p>15 but let me make sure I do. Dr. Hayes wanted to do new</p> <p>16 testing. He acquired some new Arthrex anchors. He measured</p> <p>17 them, he found a significant number of them, in his view, to</p> <p>18 be smaller than the anchors used in the '08 testing in a way</p> <p>19 that didn't appear to be random.</p> <p>20 So out of a certain number, 40-something, I think,</p> <p>21 maybe 44, he culled out seven that he thought were close</p> <p>22 enough to 3 millimeters to work for his testing, and</p> <p>23 discarded about 27 that he thought were too small, in the</p> <p>24 sense of being smaller. I don't mean discarded. Didn't use</p> <p>25 them for testing.</p>

<p style="text-align: right;">73</p> <p>1 didn't measure the force applied, he just observed the</p> <p>2 results --</p> <p>3 MR. HEBERT: Yes.</p> <p>4 THE COURT: -- to the anchor? Is this in a foam</p> <p>5 block?</p> <p>6 MR. HEBERT: Yes.</p> <p>7 THE COURT: Just observed the pull-out results to</p> <p>8 the anchor from nothing and from a quarter inch?</p> <p>9 MR. HEBERT: Right. Yes, observe, record it.</p> <p>10 MR. SABER: And that's the test that we don't</p> <p>11 object to.</p> <p>12 THE COURT: You don't object to it, you say,</p> <p>13 because since he didn't know he was entitled to try to, I</p> <p>14 suppose, guess the distance --</p> <p>15 MR. SABER: Or at least do a couple of different</p> <p>16 variations.</p> <p>17 THE COURT: Why a couple? Why couldn't he do a</p> <p>18 hundred if he didn't know?</p> <p>19 MR. SABER: If he had done a hundred of that test,</p> <p>20 we probably wouldn't be complaining either. You know, he</p> <p>21 chose to do two -- I'm not sure that Mr. Hebert got the</p> <p>22 distances exactly right, but the fact he chose to do two</p> <p>23 different distances, that's fine, and we understand that.</p> <p>24 In fact, if he had done five, we understand that, too. It's</p> <p>25 really to do this other test.</p>	<p style="text-align: right;">75</p> <p>1 BioRaptor. Nobody is going to do that except on lost sales.</p> <p>2 When we get to lost sales, we're going to have the exact</p> <p>3 opposite of what we don't have the rest of the trial:</p> <p>4 anchors. And this just has to happen, and once again, we'll</p> <p>5 just have to tell the jury, "You're only thinking about</p> <p>6 damages if you find infringement. So assuming infringement,</p> <p>7 now we're going to talk about a different issue, lost</p> <p>8 sales." And they can't think about lost sales accurately</p> <p>9 and acceptable substitute alternatives and the like without</p> <p>10 reference to, for example, BioRaptor. So I deny that</p> <p>11 motion.</p> <p>12 Motion 8: Take footnote 31 and hold Smith &</p> <p>13 Nephew to it.</p> <p>14 I deny the motion. I understand why it was made,</p> <p>15 I appreciate it, but it's a 403 ruling really, because, to</p> <p>16 quote Mr. Hebert, it's more complicated than that. To fully</p> <p>17 explain why Smith & Nephew said that and to put it in</p> <p>18 context would be a sideshow for this jury that I don't want</p> <p>19 to take them on, particularly in light of the idea that I</p> <p>20 don't want them thinking about prior proceedings much. So</p> <p>21 on 403, I deny 8.</p> <p>22 Motion 9: Preclude Smith & Nephew from using the</p> <p>23 Court's statement for reasons.</p> <p>24 And so I do grant that motion. The witnesses can</p> <p>25 transform what they've already done into assumptions. I</p>
<p style="text-align: right;">74</p> <p>1 THE COURT: I'm going to allow the testing that</p> <p>2 Arthrex does not object to, the initial testing, whatever it</p> <p>3 was, zero and a quarter, or zero, a quarter and a half.</p> <p>4 Zero is a give-away. I don't care anything about not</p> <p>5 dropping it. Even I could figure out the force applied when</p> <p>6 you attach a five-pound weight to something and don't drop</p> <p>7 it. I think the formula comes up with five pounds. It's</p> <p>8 more complicated than that, but you end up with five pounds.</p> <p>9 MR. HEBERT: That one is actually easy.</p> <p>10 THE COURT: That's good to hear.</p> <p>11 And I'll allow the other.</p> <p>12 I think Arthrex is correct, the other test</p> <p>13 involves a new test, designed to help rebut. I am, however,</p> <p>14 not prohibiting Dr. Hayes, if he knows it, from opining on</p> <p>15 what I think has got to be -- he's not going to want to give</p> <p>16 us the formula, but he can render the fairly quotidian</p> <p>17 opinion that if you increase the distance dropped, you</p> <p>18 increase the force. I mean, that's so ho-hum that I am not</p> <p>19 going to prevent him from saying it as a way of criticizing</p> <p>20 the test he's criticizing, since it doesn't involve new</p> <p>21 testing. I mean, it's essentially the opinion he offers</p> <p>22 based on testing, but I'm going to divorce it from the</p> <p>23 testing. He's not allowed to use that test. That's my</p> <p>24 ruling on 6.</p> <p>25 7: Don't use images, models or samples of</p>	<p style="text-align: right;">76</p> <p>1 just don't want the jury to hear that I found certain</p> <p>2 things, since those findings, in my view, have been erased.</p> <p>3 Motion 10: John Mahoney should be precluded from</p> <p>4 testifying beyond his testimony at the '08 trial, or that of</p> <p>5 his predecessor in the '07 trial.</p> <p>6 And I deny that motion. As I've said, we've sort</p> <p>7 of blown damages wide open here.</p> <p>8 Let's take a break and then I'll do -- go over the</p> <p>9 Daubert motions.</p> <p>10 THE CLERK: This court is in recess.</p> <p>11 (A recess is then taken.)</p> <p>12 THE COURT: All right. First let me be clear what</p> <p>13 I left hanging. I left hanging 40, 44 and 46 for</p> <p>14 plaintiffs.</p> <p>15 40, I grant. I want to be clear about that also.</p> <p>16 The concept is that I'm not going to allow comparison to a</p> <p>17 group of anchors that fit by resilience or wings or</p> <p>18 automatic deployment or the like, as compared to Arthrex</p> <p>19 anchors. So that comparison I'm not going to allow. If</p> <p>20 someone tries to make that comparison using phrases like</p> <p>21 "expansion fit" and the like, then I won't allow it.</p> <p>22 If someone -- if the witness is talking about the</p> <p>23 patent and the term "resilience," and says "expansion" in</p> <p>24 the course of describing what resilience is, then don't jump</p> <p>25 out of your chair and object to the use of the word</p>

<p style="text-align: right;">81</p> <p>1 lodging must have occurred as to whether it really did occur 2 or not. 3 So that's my ruling on 6 and 7 of plaintiffs' 4 Daubert motions. 5 There's a motion to preclude all testimony from 6 Dr. Goble. I've talked about Dr. Goble at some length. I 7 grant it in part and deny it in part. 8 There's a motion to preclude the new damages 9 expert, David Paris, regarding his lost profits testimony 10 before 2006 or the reasonable royalty rate. That all has to 11 do with a view of the law of the case, the law of the 12 mandate. That's different from the view I've taken, so I 13 deny that motion. 14 There's a motion to preclude Arthrex's damages 15 expert, David Paris, from ignoring admissions made by 16 previous damages experts and introducing new arguments on 17 damages. 18 Now, here I want to make a distinction. It's true 19 that these prior statements by previous damages experts are 20 admissions of a party opponent and admissible as such. It's 21 a different question whether those admissions in some manner 22 allow me to forbid an expert from saying something 23 different. And I don't think they do. I think a party can 24 -- that's why we have the rule. A party can say something 25 at trial that's different than an admission they made</p>	<p style="text-align: right;">83</p> <p>1 new licensing negotiations. Explain to me why they're 2 relevant, why they're reliable for the point they're used 3 for. 4 MR. SABER: Sure. I'd be happy to, Your Honor. 5 I thought we had said in our opposition, when we 6 pointed to the parts of Mr. Paris's report where he spoke at 7 length about these agreements and talked specifically about 8 the elements that are in there where it identifies the 9 rates, it identifies the products, it identifies the 10 patents, where they are patented, and it provides exactly 11 the kinds of detail that is required. 12 What the Lucent case -- at least as I read it -- 13 is about is you can't just throw up license agreements and 14 say, therefore, consider these. You have to show why they 15 matter and why they're appropriate to consider. 16 THE COURT: What sort of devices are involved in 17 the new licensing negotiations? "New" meaning new to this 18 witness from a prior trial. 19 MR. SABER: First of all, Your Honor, they're not 20 new. In fact, Mr. Troxel was asked about all of them during 21 trial. So they're old, they're not new. 22 They're all medical devices. Several of them -- 23 many of them are suture anchors. Now, they try to say 24 they're different because they're screw-in types rather than 25 what I'll call the resilient type, and that's, of course, a</p>
<p style="text-align: right;">82</p> <p>1 earlier, and that admission can just be used against them. 2 So I deny the motion, but certainly without 3 prohibiting in any way Smith & Nephew from using the 4 admission as an admission of a party opponent in any way it 5 sees fit within the federal rules at trial. 6 THE CLERK: Clarification for the clerk. What 7 number is that? 8 THE COURT: 11. 9 No. 12 is a motion to preclude testimony regarding 10 royalty damages without specific evidentiary foundation -- 11 at least that's how I call the motion. 12 So I've already said that the defense can argue 13 for a different reasonable royalty. Arthrex -- excuse me, 14 Smith & Nephew at this point has a more truly Daubert motion 15 as a sort of a fall-back position, which is that the new 16 expert relies on other previous licensing negotiations but 17 without that expert providing enough detail for 18 Smith & Nephew or for a jury to evaluate its true 19 reliability in terms of the negotiations involving some sort 20 of similar set of circumstances. 21 And Arthrex's only response didn't help me a lot. 22 It's that the licenses involved are in the record. So I 23 didn't go to the record and look for myself whether the 24 criterion for satisfying this Daubert motion were met. I 25 just thought I'd ask you here today to help me with these</p>	<p style="text-align: right;">84</p> <p>1 fair thing to discuss the differences as to how appropriate 2 those should be. But they are all medical fixation devices, 3 many of them suture anchors. The exact kinds of devices 4 that should be looked at in this case have been looked at as 5 appropriate to consider as the types of materials -- 6 THE COURT: The ones that aren't suture anchors, 7 what are they? 8 MR. SABER: They're other kinds of fixation 9 devices. 10 THE COURT: Like what? 11 MR. SABER: That might be used in the knee, for 12 example, to fixate tissue. Same kind of concept, but 13 because it's a different part of the body, you wouldn't be 14 necessarily using a suture anchor, you'd be using some other 15 kind of device. 16 So they're all very related, but they're not 17 all -- and many of them are suture anchors. So they're all 18 close, and there is a debate, as there appropriately should 19 be in the cases, are they close enough. 20 THE COURT: All right. Thank you. Let me get 21 back to you in just a minute. 22 The main argument -- Smith & Nephew's argument is 23 that you just don't have any information sufficient to judge 24 reliability, and the response, without going further with 25 it, is that quite a bit of information has in fact been</p>

Exhibit 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

SMITH & NEPHEW, INC. and
JOHN O. HAYHURST, M.D.,

Plaintiffs,

v.

ARTHREX, INC.,

Defendant.

No. CV 04-29-MO

STATEMENT OF REASONS
SUPPORTING PERMANENT
INJUNCTION

MOSMAN, J.,

On November 19, 2008, this Court issued an Order of Permanent Injunction in this action. The following is the Court's Statement of Reasons Supporting that Injunction.

A. Background

1. On January 12, 2004, plaintiffs Smith & Nephew, Inc. and Dr. John O. Hayhurst commenced this action against defendant Arthrex, Inc. for infringement of U.S. Patent No. 5,601,557 ("the '557 patent"). In their Complaint, plaintiffs requested an injunction to stop Arthrex's continued infringement. (Dkt. No. 1).

2. Dr. Hayhurst is the owner and Smith & Nephew is his exclusive licensee of the '557 patent. (Dkt. No. 1).

3. Following an initial trial which resulted in a hung jury, the issues of infringement,

willful infringement and damages were tried to a jury in a re-trial of this case from June 3, 2008, to June 11, 2008.

4. On June 11, 2008, the jury in the re-trial of this case returned a verdict of infringement in favor of the plaintiffs. (Dkt. No. 489).

5. Specifically, the jury found that Arthrex infringed claims 1 through 7 of U.S. Patent No. 5,601,557 (“the ‘557 patent”) by marketing and selling four suture anchors: 1) the Bio-SutureTak; 2) the PEEK SutureTak; 3) the PEEK PushLock; and 4) the Bio-PushLock. In addition, Arthrex’s infringement was found to be willful (see Dkt. No. 489).

6. Previously, this Court had dismissed, or Arthrex had abandoned, all of Arthrex’s invalidity and unenforceability defenses. (Dkt. No. 241; Dkt. No. 278).

7. Thus, the Court finds that the ‘557 patent is valid, enforceable and willfully infringed.

8. The jury also awarded the plaintiffs monetary damages in the amount of \$14,695,858. This included \$4,788,014 to compensate the plaintiffs for Smith & Nephew, Inc.’s lost profits for lost sales through the end of 2005 as a result of Arthrex’s infringement. (Dkt. No. 489).

B. The Patented Invention and Competition Between the Parties

9. The ‘557 patent is directed to certain methods of using a medical device called a suture anchor. Suture anchors allow a surgeon to repair soft tissue (such as ligaments, tendons or capsules) that has torn away from the bone, by re-attaching the tissue back to the bone so it can heal.

10. In about 1992, Dr. Hayhurst’s original exclusive licensee, Acufex Microsurgical Inc., began marketing and selling Dr. Hayhurst’s patented suture anchors, which were implanted using the claimed methods of the ‘557 patent. These licensed anchors were all plastic, and they all pushed in or tapped into a pre-drilled hole in the bone (Re-Trial Trans. p. 211, line 6 to p. 212, line 14, Dkt. No. 524, Exhibit 2; Mahoney Decl., Dkt. No. 523, ¶ 4).

11. Smith & Nephew acquired Acufex and thereby became Dr. Hayhurst's exclusive licensee. (Re-Trial Trans. p. 212, lines 15-17, Dkt. No. 524, Exhibit 2).

12. Arthrex introduced its first suture anchor in 1996 or 1997 (Re-Trial Trans. p. 800, line 22 to p. 801, line 5, Dkt. No. 524, Exhibit 2).

13. The original Arthrex anchors fell into a different market niche than Dr. Hayhurst's plastic, push-in anchors. Arthrex's initial anchors, called FASTak, were metal, and they were screwed into the bone (Re-Trial Trans. p. 259, line 19 to p. 260, line 10, Dkt. No. 524, Exhibit 2).

14. Arthrex's screw-in anchors were not very successful. By 1999, Arthrex was still at the "bottom of the pack," according to Arthrex's marketing witness at the re-trial, William Benevitz (Re-Trial Trans. p. 766, lines 3-8, Dkt. No. 524, Exhibit 2).

15. To change that, Arthrex began making plastic, push-in suture anchor products. In the year 2000, Arthrex did not have any of that part of the market (Re-Trial Trans. p. 810, lines 5-13, Dkt. No. 524, Exhibit 2).

16. Arthrex introduced its first infringing anchor, the plastic, push-in Bio-SutureTak, in late 2001. (Re-Trial Exhibit 175, Dkt. No. 524, Exhibit 3; Re-Trial Trans. p. 742, line 7 to p. 743, line 24, Dkt. No. 524, Exhibit 2).

17. At the time of such introduction, Arthrex was already aware of the '557 patent. This awareness was at the highest level of the company, including by its President Reinhold Schmieding. (Re-Trial Exhibit 175, Dkt. No. 524, Exhibit 3; Re-Trial Trans. p. 742, line 7 to p. 745, line 4, Dkt. No. 524, Exhibit 2).

18. Arthrex credits the Bio-SutureTak with turning around its fortunes in the suture anchor market.

19. The other major designs in addition to the Bio-SutureTak included Arthrex's other three plastic, push-in anchors that were also found to infringe: the PEEK SutureTak; the PEEK PushLock; and the Bio-PushLock anchors.

20. Two of Arthrex's three largest selling suture anchors today are the infringing

Bio-SutureTak and the infringing PushLock anchors, according to Arthrex's Mr. Benavitz (Re-Trial Trans. p. 767, line 24 to p. 768, line 1, Dkt. No. 524, Exhibit 2).

21. Along with the anchors, Arthrex produced and distributed surgical instructions showing how its infringing anchors could be used to repair exactly the same dislocated shoulder injury (Bankart lesion) for which Dr. Hayhurst had made his invention in the first place (see Re-Trial Exhibits 26, 27 and 42, Dkt. No. 524, Exhibits 4-7; Re-Trial Trans. p. 194, lines 6-25, Dkt. No. 524, Exhibit 2).

C. Irreparable Harm

22. The first factor in determining whether to award an injunction is to determine whether there would be irreparable harm without an injunction.

23. Arthrex is Smith & Nephew's biggest competitor for suture anchors throughout the United States (Re-Trial Trans. p. 265, lines 2-8, Dkt. No. 524, Exhibit 2).

24. The actual competition between Arthrex and Smith & Nephew is in a specific segment of that market – plastic, push-in anchors – which Dr. Hayhurst and his licensees, Acufex and Smith & Nephew, created, and which Arthrex has now taken over as a result of its ongoing infringement of Dr. Hayhurst's '557 patent.

25. When Arthrex gained market share, it did so by taking that market share from other competitors, including Smith & Nephew and the plaintiffs' other licensee, Johnson & Johnson (Mitek) (Re-Trial Trans. p. 765, line 22 to p. 766, line 19, Dkt. No. 524, Exhibit 2).

26. Smith & Nephew continues to market the Acufex suture anchors implanted by Dr. Hayhurst's patented method, and has invested significant time, money and effort in developing an additional suture anchor, called the BioRaptor, which is also covered by Dr. Hayhurst's patents and implanted by the methods covered by his '557 patent. (Mahoney Decl., Dkt. No. 523, ¶¶ 4, 5, and 7).

27. The new Smith & Nephew BioRaptor was introduced to the market in late 2004 (Re-Trial Trans. p. 734, lines 3-17, Dkt. No. 524, Exhibit 2; Mahoney Decl., Dkt. No. 523, ¶ 5).

The BioRaptor is also a plastic, push-in anchor, and it comes pre-loaded with a suture and mounted on its own installation tool (Re-Trial Trans. p. 271, line 3 to p. 272, line 21, Dkt. No. 524, Exhibit 2).

28. In addition, since that time, Smith & Nephew has continued to invest substantial time and money in developing still other plastic, push-in anchors. These include the KINSA anchor which was introduced in the fall of 2006, and the BioRaptor 2.3 PK and Footprint PK anchors, both of which were introduced in early 2008. Including the BioRaptor, Smith & Nephew has invested approximately \$4 million in development costs for these new anchors. (Mahoney Decl., Dkt. No. 523, ¶¶ 5, 6, 7).

29. In terms of product-to-product competition, Smith & Nephew's BioRaptor suture anchor matches up almost exactly with Arthrex's Bio-SutureTak. Both the Bio-SutureTak and the BioRaptor are made of bio-absorbable plastic, and both are push-in anchors. Both include pre-attached sutures, and both anchors are pre-mounted on installation tools. Further, both are sold for the same surgeries. (See, e.g., Re-Trial Trans. p. 271, line 6 to p. 272, line 21, p. 706, line 24 to p. 707, line 10, and p. 734, line 20 to p. 735, line 2, Dkt. No. 524, Exhibit 2).

30. This identity of form and function between the BioRaptor and Bio-SutureTak was the basis for Smith & Nephew's lost profits claim at the re-trial (Re-Trial Trans. p. 703, line 24 to p. 705, line 11 and p. 706, line 24 to p. 707, line 15, Dkt. No. 524, Exhibit 2), and the evidence on this issue was not challenged by Arthrex, either in cross-examination of Smith & Nephew's expert, Richard Troxel (see Re-Trial Trans. p. 734, line 18 to p. 739, line 1, Dkt. No. 524, Exhibit 2), or in the examination of its own damages expert, Russell Parr (Re-Trial Trans. p. 1089, lines 3-7; p. 1093, lines 5-18, Dkt. No. 524, Exhibit 2).

31. The jury found, as a fact, that Smith & Nephew had lost almost \$5 million in sales of its BioRaptor suture anchor in a little over a year, from late 2004 when the BioRaptor was introduced through the end of 2005, as a result of Arthrex's infringement (see Re-Trial Exhibit 130, Exhibit D, Dkt. No. 524, Exhibit 9).

32. Arthrex continues to be Smith & Nephew's major competition in the plastic push-in anchor market, and Smith & Nephew continues to lose BioRaptor sales as a result of Arthrex's ongoing infringement (Mahoney Decl., Dkt. No. 523, ¶¶ 11, 12).

33. Due to Arthrex's infringement, Smith & Nephew cannot sell the BioRaptor suture anchor as extensively as it could if the infringement was not ongoing (Mahoney Decl., Dkt. No. 523, ¶¶ 4, 7 and 11).

34. Arthrex's infringement is ongoing, including after 2005 and even after the jury's verdict in this case, and therefore Smith & Nephew has lost additional sales after 2005 to Arthrex and continues to lose sales to Arthrex.

35. These lost sales translate into lost market share in the suture anchor market for Smith & Nephew.

36. Smith & Nephew's lost sales extend beyond that of the suture anchors themselves, as Smith & Nephew and Arthrex both also sell drills, drill guides and other associated products for use with their suture anchors (Mahoney Decl., Dkt. No. 523, ¶ 12).

37. The loss of sales of such other associated products was an unchallenged factor in the plaintiffs' expert setting the reasonable royalty damages rate at the re-trial (Re-Trial Trans. p. 719, line 18 to p. 720, line 4, Dkt. No. 524, Exhibit 2; Re-Trial Exhibit 130, Exhibit D, Dkt. No. 524, Exhibit 9), which rate the jury adopted.

38. Thus, Arthrex's continuing infringement also costs Smith & Nephew its profits and market share from these additional, related products.

39. The plaintiffs have licensed Johnson & Johnson under the '557 patent. Johnson & Johnson's Ethicon division (formerly Mitek) pays the plaintiffs an ongoing royalty on its sales of its licensed anchors. (Re-Trial Trans. p. 721, lines 7-24, Dkt. No. 524, Exhibit 2).

40. Arthrex's infringing suture anchors have allowed Arthrex to displace Johnson & Johnson (Mitek) as the market leader and greatly reduce Johnson & Johnson's market share (Re-Trial Trans. p. 766, lines 3-16, Dkt. No. 524, Exhibit 2).

41. Any such reduction in Johnson & Johnson's market share also reduces the royalties paid to the plaintiffs under this license and represents a further harm in the form of ongoing loss of income to the plaintiffs as a result of Arthrex's infringement.

42. In addition to new product development, in 2004, Smith & Nephew began investing millions of dollars in clinical marketing and surgeon education to try to recapture and increase market share (Re-Trial Trans. p. 257, line 5 to p. 258, line 13, Dkt. No. 524, Exhibit 2).

43. But Smith & Nephew had a difficult time trying to make any inroads against Arthrex. In fact, third party marketing reports indicate that with Arthrex's big "lead" in this market, Smith & Nephew was not making much progress (Re-Trial Trans. p. 735, line 18 to p. 736, line 2, Dkt. No. 524, Exhibit 2; Mahoney Decl., Dkt. No. 523, ¶¶ 8, 9, 10; Re-Trial Exhibit 134B, Dkt. No. 524, Exhibit 8).

44. Thus, Arthrex, due to its infringement, now has such a large piece of the suture anchor market and is so firmly entrenched in it that Smith & Nephew's efforts to increase market share, despite its investment of millions of dollars in additional marketing efforts, and new product introductions, have largely been unsuccessful.

45. Arthrex's leading position in the suture anchor market was obtained, at least in part, by its willful infringement of the '557 patent.

46. Smith & Nephew's predecessor company, Acufex, marketed the first plastic, push-in suture anchors, and Smith & Nephew itself has spent a great deal of money in bringing new suture anchors to the market. (Mahoney Decl., Dkt. No. 523, ¶ 6).

47. Arthrex's reputation as the market leader and as an innovator in the suture anchor market was built largely on the infringing suture anchors. This has directly detracted from Smith & Nephew's reputation as an innovator in the marketplace.

48. As a result of Arthrex's infringement, it appears to others as if it is Arthrex that is the "innovator" in the suture anchor market instead of Smith & Nephew.

49. Arthrex's infringement has harmed Smith & Nephew's reputation as an innovator in the suture anchor market.

50. Arthrex's continued infringement will result in substantially reduced sales revenue for Smith & Nephew, as well as lost market share, lost investment in new product development, lost sales of collateral products and licensing revenue, and loss of reputation, customer relationships and goodwill.

51. Irreparable harm exists in this case, since the infringement is by a direct competitor and the infringement has caused the patentee to suffer losses of sales, market share, investment in new product development, sales of collateral products, licensing revenue, reputation, customer relationships and goodwill.

52. In view of all of the foregoing, the Court finds that the irreparable harm factor is clearly established.

D. Adequacy of Monetary Relief

53. The second factor in determining whether to award an injunction is whether money damages would be inadequate. This factor is closely related to the irreparable harm factor discussed above.

54. Arthrex and Smith & Nephew are major competitors in the market for plastic press-in suture anchors.

55. The plaintiffs cannot quantify the damage they will incur, particularly in terms of lost market share, lost reputation and lost customer relationships and goodwill, if forced to continue to share the '557 technology with Arthrex for the remainder of the '557 patent's life.

56. It is not Smith & Nephew's general policy to grant licenses to competitors. (Re-Trial Trans. p. 723, lines 13-15, Dkt. No. 561, Exhibit 1).

57. The license that Smith & Nephew granted to Ethicon in 2002, in settlement of a prior patent infringement lawsuit, does not demonstrate that monetary relief is adequate. The Ethicon license includes restrictions on the types of suture anchors that Ethicon can sell, which

precludes suture anchors like Arthrex's. (See Re-Trial Trans. p. 722, lines 8-13, Dkt. No. 561, Exhibit 1). In addition, the Ethicon license was granted in 2002, before Smith & Nephew introduced the BioRaptor suture anchor, and so at the time of the Ethicon license Smith & Nephew was not in the same competitive position as it now is with Arthrex.

58. Accordingly, the Court finds that monetary damages are insufficient to adequately compensate Smith & Nephew for the lost market share, lost business opportunities, and damage to reputation customer relationships and goodwill described above.

59. Thus, this factor also favors an injunction.

E. Balance of Hardships

60. The third factor in determining whether to award an injunction involves assessing the balance of hardships.

61. Arthrex started its infringing activities with full knowledge at the highest level of the company, including by its President Reinhold Schmieding, of the '557 patent. (Re-Trial Exhibit 175, Dkt. No. 524, Exhibit 3).

62. Despite such knowledge, Arthrex went ahead with its infringing activities (Re-Trial Exhibit 175, Dkt. No. 524, Exhibit 3).

63. Arthrex ultimately took a position at trial that it was not relying on an advice-of-counsel defense. It presented no other evidence of good faith. The jury found the infringement willful.

64. Arthrex cannot now claim hardship because it elected to ignore the '557 patent in the first place without the benefit of any reliable opinion of counsel.

65. By its willful infringement, Arthrex has improperly benefited for about seven years, to the direct detriment of the patentee and his licensee, Smith & Nephew.

66. While there will be some impact on Arthrex's business, Arthrex was well aware of that risk when it started to and continued to market the accused products from 2001 until even today.

67. Arthrex is a large company, which operates worldwide and had U.S. sales in fiscal year 2008 of about \$444M. (Benavitz Decl., Dkt. No. 545, ¶ 7).

68. Arthrex describes itself as having locations worldwide and over 3000 products (Arthrex website, Dkt. No. 524, Exhibit 10).

69. The issuance of a permanent injunction in this case will not even come close to driving Arthrex out of business.

70. An injunction would not even drive Arthrex out of the suture anchor business because Arthrex continues to sell non-infringing suture anchors.

71. In terms of the practical effect of the injunction on the marketplace, the injunction will only impact Arthrex's SutureTak family of anchors (consisting of the Bio-SutureTak and PEEK SutureTak anchors).

72. The injunction will not have the effect of removing Arthrex's PushLock anchors from the market, since Arthrex changed the design of those anchors during the course of this lawsuit. Instead, the PushLock anchors that are currently on the market are the subject of a new lawsuit, Smith & Nephew, Inc. v. Arthrex, Inc., Civil Action No. 08-00714-MO.

73. Arthrex's U.S. sales of suture anchors in its SutureTak family in fiscal year 2008 were about \$38.6 million. (See Troxel Decl. filed Nov. 17, 2008, Dkt. No. 602, ¶ 6). Given that Arthrex's total U.S. sales over that time period amount to \$444 million, this represents about 8.7% of Arthrex's U.S. sales. (See Id. at ¶¶ 4-6).

74. Thus, an injunction in this case will not impose any unreasonable hardship on Arthrex.

75. On the other hand, the burden on Smith & Nephew, if an injunction does not issue, will be far greater than any harm to Arthrex.

76. Smith & Nephew has experienced over seven years of infringement by Arthrex.

77. Without an injunction, other competitors may feel free to infringe the '557 patent.

78. Without a permanent injunction, Smith & Nephew will continue to suffer lost

sales, lost market share, lost investment in new product development, lost sales of collateral products, lost licensing revenue, lost reputation, and lost customer relationships and goodwill.

79. These harms significantly tip the balance of hardships in favor of the plaintiffs.

80. Thus, the Court finds that the balance of harms factor supports grant of a permanent injunction.

F. The Public Interest

81. The final factor in determining whether to award an injunction is determining where the public interest lies.

82. First of all, the Court recognizes that there is substantial public interest in enforcing valid patents, and this public interest favors the grant of an injunction.

83. Arthrex's customers, the surgeons and their patients, will not be harmed by an injunction because there are a variety of other acceptable substitute anchors available, as its expert, Mr. Parr, suggested (Parr Expert Report at pages 7, 9, Dkt. No. 524, Exhibit 11; Re-Trial Trans. p. 1316, line 10 through p. 1318, line 6, Dkt. No. 524, Exhibit 12).

84. Arthrex's damages expert, Mr. Russell Parr, took the position with Arthrex's approval, that the surgeons are completely indifferent to which anchor they use (Parr Expert Report at pages 7, 9, Dkt. No. 524, Exhibit 11; Re-Trial Trans. p. 1316, line 10 through p. 1318, line 6, Dkt. No. 524, Exhibit 12).

85. Arthrex itself has admitted that there are many available substitute anchors on the market. In its Opposition to Plaintiffs' Motion for Permanent Injunction, Arthrex admitted that there are many other acceptable suture anchors on the market that surgeons can select in order to replace the SutureTak and PushLock anchors:

If forced to do without the benefits of the PushLock anchors or SutureTak anchors, a surgeon could turn to anchors made by Ethicon, Linvatec, Arthrocare, Biomet and Arthrotek. These companies all offer anchors that a surgeon would find at least as desirable, if not more, to the Smith & Nephew BioRaptor and are useable for the same surgeries as Arthrex's SutureTak and PushLock anchors.

(Arthrex Br., Dkt. No. 543, at 5).

86. Arthrex also submitted a declaration from its expert, Dr. Greenleaf, who is an orthopedic surgeon, which includes the very same admission. (Greenleaf Decl., Dkt. No. 547, ¶ 8).

87. Arthrex's expert, Dr. Burkhead, who is also an orthopedic surgeon, testified at his deposition that if a surgeon could not use the Bio-SutureTak anchor, that surgeon would be able to instead use "metal anchors that are very reliable and have been used for years." Dr. Burkhead also testified that he personally "would probably go back to the Mitek G2 because I know it is relatively inexpensive and consistently works." (See Burkhead Dep. at p. 284, lines 3-19, attached as Exhibit 2 to Legaard Decl. filed Nov. 17, 2008, Dkt. No. 596).

88. Smith & Nephew suture anchors are also available on the market and can be substituted for Arthrex's SutureTak anchors. For example, as set forth above, Smith & Nephew's BioRaptor suture anchors are comparable to Arthrex's Bio-SutureTak anchors.

89. As set forth above, the jury found as a fact that Smith & Nephew has lost sales of its BioRaptor anchors to Arthrex's infringing anchors. Necessary to and implicit in that finding is the fact that such anchors may be used as substitutes for each other.

90. In fact, during the permanent injunction hearing of October 28, 2008, Arthrex's counsel admitted that the jury's verdict on lost profits damages, which has been upheld by this Court, was conclusive on the issue that Arthrex's infringement took sales directly from Smith & Nephew due to the infringing features. (Tr. of Inj. Hrg. of 10/28/08, at 31-32, attached as Exhibit 1 to Legaard Decl. filed Nov. 17, 2008, Dkt. No. 596).

91. In addition, Smith & Nephew has the capacity to increase suture anchor production to more than meet all the demands for the enjoined anchors (O'Connor Decl., Dkt. No. 522, ¶¶ 4, 7).

92. As set forth above, due to changes in their design, this injunction will not impact the versions of the Arthrex PushLock anchors that are currently on the market.

93. Accordingly, the Court finds that there would be either no or minimal adverse effect on surgeons or patients as a result of the injunction.

94. Thus, the Court finds that the public interest factor also supports granting a permanent injunction in this case.

IT IS SO ORDERED.

DATED this 3rd day of December, 2008.

/s/ Michael W. Mosman
MICHAEL W. MOSMAN
United States District Judge

Exhibit 10

SAN DIEGO, CALIFORNIA 92101

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<p style="text-align: right;">Page 11</p> <p>1 HE IS FREE TO RENDER HIS OPINION AND THE BASES FOR THOSE 2 OPINIONS, BUT AS TO ULTIMATE CONCLUSIONS, AND MORE 3 PARTICULARLY LEGAL CONCLUSIONS, I THINK THE MOTION IS WELL 4 STATED. 5 HERE, IN THE MOTION, ARTHREX POINTS OUT THAT THERE 6 IS OPINION TESTIMONY THAT DEFENDANT ARTHREX INDUCED 7 INFRINGEMENT, THAT IT CONTRIBUTED TO THE INFRINGEMENT, AND 8 THAT IT ACTIVELY AND KNOWINGLY AIDED AND ABETTED THE DIRECT 9 INFRINGEMENT. AND THAT IT WOULD BE REASONABLE, ACCORDING TO 10 THE EXPERT, FOR THE JURY TO INFER THE DEFENDANT'S KNOWLEDGE OF 11 INFRINGEMENT. 12 THOSE FOUR AREAS AND THE QUOTATIONS ATTRIBUTED TO 13 DR. TICKER, THOSE WOULD BE ULTIMATE LEGAL CONCLUSIONS. THEY 14 WOULD NOT ASSIST A TRIER OF FACT. SO THE TENTATIVE -- THAT IS 15 OATH SAYER TYPE TESTIMONY. SO THE TENTATIVE HERE WOULD BE TO 16 GRANT THAT MOTION AS TO THOSE ULTIMATE LEGAL CONCLUSIONS, BUT 17 NOT AS TO THE UNDERLYING INFORMATION AND OPINION OF THE 18 DOCTOR. 19 THE SECOND MOTION IS TO PRECLUDE KFX FROM PRESENTING 20 ARGUMENT OR EVIDENCE OF OTHER LITIGATION, SPECIFICALLY THAT IS 21 THE S&N CASE, SMITH & NEPHEW. 22 I READ THAT CASE AS IT APPEARED IN THE UNPUBLISHED 23 DECISION FROM THE FEDERAL CIRCUIT. 24 THE TENTATIVE HERE -- BEFORE DOING THAT, LET ME 25 INQUIRE. <p style="text-align: center;">AUGUST 9, 2013</p> </p>	<p style="text-align: right;">Page 13</p> <p>1 MR. JENNINGS: YES. 2 THE COURT: AND WHAT WAS THE OUTCOME OF THAT? 3 MR. JENNINGS: FIRST TIME, HUNG JURY. SECOND TIME, 4 SMITH & NEPHEW WINS INFRINGEMENT, A 16 PERCENT ROYALTY IS 5 SPECIFIED BY THE JURY. THE FEDERAL CIRCUIT VACATES THAT AND 6 SENDS THAT BACK FOR A THIRD TRIAL. THIS TIME SMITH & NEPHEW 7 WINS. THE JURY ASSESSES DAMAGES, DOES NOT SPECIFY A 8 PARTICULAR ROYALTY RATE. THE DISTRICT COURT JUDGE, JUDGE 9 MOSMAN, GRANTS A JMOL OF NO INFRINGEMENT. GOES TO THE FEDERAL 10 CIRCUIT. THE FEDERAL CIRCUIT REVERSES THAT AND REINSTATES THE 11 JURY VERDICT. 12 THE COURT: WHAT WAS THE FINAL DOLLAR AMOUNT? 13 MR. JENNINGS: I BELIEVE IT WAS -- MY BEST GUESS IS 14 \$60 MILLION ON THE THIRD VERDICT. 15 THE COURT: BUT THERE WASN'T A ROYALTY RATE ASSIGNED 16 ON THAT LAST ONE. 17 MR. JENNINGS: RIGHT. THE DISCUSSION ON THIS MOTION 18 WAS THE ROYALTY RATE THAT WAS ASSESSED AS A HYPOTHETICAL 19 NEGOTIATION IN THE TRIAL THAT WAS VACATED ON THE LIABILITY AND 20 THE FEDERAL CIRCUIT DID NOT ADDRESS THE DAMAGES. 21 THE COURT: OKAY. THANK YOU. 22 HERE THE TENTATIVE IS TO DENY THE MOTION IN PART. 23 IT SEEMS TO ME THAT THE PLAINTIFF'S EXPERT CAN USE THE 24 REASONABLE ROYALTY RATE FROM THE S&N LITIGATION, THAT IS THE 25 16 PERCENT, AS A BASIS FOR HIS OPINION THAT 11.7 PERCENT IS <p style="text-align: center;">AUGUST 9, 2013</p> </p>
<p style="text-align: right;">Page 12</p> <p>1 WHAT WAS THE SECOND VERDICT? I UNDERSTAND THERE WAS 2 A VERDICT IN FAVOR OF S&N AGAINST ARTHREX. WHAT WAS THAT 3 SECOND VERDICT, DO YOU KNOW? 4 MR. JENNINGS: THE SECOND VERDICT -- 5 THE COURT: YES. 6 MR. JENNINGS: -- WAS A ROYALTY OF 16 PERCENT AND A 7 FINDING OF INFRINGEMENT. THE INFRINGEMENT WAS VACATED. 8 THE COURT: I THOUGHT THE FIRST VERDICT WAS THE 9 16 PERCENT WITH INFRINGEMENT. IT WENT UP ON APPEAL. THE 10 COURT OF APPEAL REVERSED BASED ON A CLAIM CONSTRUCTION NOT 11 RELATED TO THE ISSUES IN THIS CASE. 12 MR. JENNINGS: YOUR HONOR, IT IS BECAUSE THERE WERE 13 THREE TRIALS. THE FIRST ONE WAS A HUNG JURY, SO I AM ONE OFF 14 FROM YOU. 15 THE COURT: OKAY. 16 MR. JENNINGS: THE SECOND VERDICT -- SO IN MY MIND 17 IT WAS THE THIRD -- THE JURY FOUND INFRINGEMENT BUT DID NOT 18 SPECIFY A PARTICULAR ROYALTY RATE. THE JUDGE THREW THAT OUT 19 ON JMOL. AND THEN THE FEDERAL CIRCUIT REVERSED AND REINSTATED 20 THE JURY VERDICT. 21 THE FIRST CASE, THERE WAS A FINDING OF INFRINGEMENT 22 AND THE JURY DETERMINED A 16 PERCENT REASONABLE ROYALTY IN 23 THAT CASE. AND THAT WAS VACATED BY THE FEDERAL CIRCUIT ON THE 24 INFRINGEMENT ISSUE, AND SENT BACK FOR THE FOLLOW-ON TRIAL. 25 THE COURT: RETRIED AGAIN? <p style="text-align: center;">AUGUST 9, 2013</p> </p>	<p style="text-align: right;">Page 14</p> <p>1 REASONABLE. 2 IT SEEMS TO ME THAT THAT IS INFORMATION THAT IS 3 RELIABLE AND IT IS APPROPRIATELY CONSIDERED UNDER THE 702 4 FACTORS BY AN EXPERT. 5 THE QUESTION IS HOW MUCH OF THE UNDERLYING 6 INFORMATION CAN HE PARADE BEFORE THE JURY. AND HERE IT SEEMS 7 TO ME THAT THE EXPERT CAN REFERENCE THE 16 PERCENT RATE AS 8 FOUND IN ANOTHER CASE WITHOUT DISCLOSING THE WHOLE HISTORY OF 9 THE CASE -- THAT A JURY FOUND 16 PERCENT, THAT THERE WAS A 10 VERDICT, THAT IT WENT UP, IT WENT DOWN, ALL OF THOSE THINGS -- 11 BUT RATHER COULD SIMPLY INFORM THE JURY OF THE BASIS FOR HIS 12 OPINION. AND ONE OF THE FACTUAL BASES WOULD BE THAT A 13 16 PERCENT RATE WAS DETERMINED IN RELATED LITIGATION, 14 SOMETHING OF THAT NATURE, WITHOUT THE DISCLOSING THE ULTIMATE 15 FACTS TO THE JURY, THIS JURY, THAT THE 16 PERCENT WAS ARRIVED 16 AT BY ANOTHER JURY IN A DIFFERENT CASE THAT WENT UP ON APPEAL, 17 THAT WAS REVERSED, ALL OF THAT. 18 SO THE THOUGHT HERE WAS THAT MR. STRONG COULD USE 19 THE 16 PERCENT BUT WOULD BE LIMITED IN THE MANNER IN WHICH HE 20 DESCRIBES WHERE THAT 16 PERCENT COMES FROM. SO THE JURY WOULD 21 HAVE SOME INFORMATION AS TO THE 16 PERCENT AND WHERE IT WAS 22 DERIVED FROM, BUT NOT ALL OF IT AS TO THE RELATED LITIGATION 23 HISTORY, THE VERDICT AND THE APPEAL. 24 ALSO, IT SEEMS TO ME THAT KFX CAN PROPERLY USE THE 25 S&N LITIGATION TO IMPEACH OR TO REBUT THE ASSERTIONS BY <p style="text-align: center;">AUGUST 9, 2013</p> </p>

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1 ARTHREX' EXPERT THAT 11.7 IS UNREASONABLE, AND THAT THE
2 APPROPRIATE RATE IS MORE IN THE RANGE OF 1 TO 3 PERCENT.

3 IT SEEMS TO ME THAT ON CROSS COUNSEL FOR KFX CAN
4 TEST THE OPINIONS OF ARTHREX EXPERTS THROUGH THE USE OF THE
5 S&N LITIGATION.

6 I HAVE THE SAME OBSERVATION HERE, THAT COUNSEL IN
7 CROSS OUGHT NOT TO BE REFERENCING JURY FINDINGS OR VERDICTS IN
8 THE S&N CASE BECAUSE OF THE COMPLICATED HISTORY OF THAT AND
9 ULTIMATELY THE COURT OF APPEAL INTERVENTION.

10 I THINK THOSE ARE ALL THE TENTATIVES I HAVE ON
11 NO. 2, AND WE CAN COME BACK TO THAT IN A MOMENT.

12 THE THIRD MOTION IN LIMINE IS TO PRECLUDE KFX FROM
13 PROFFERING ARGUMENT OR EVIDENCE OF AN INVENTION DATE EARLIER
14 THAN SEPTEMBER 17, '04. THE TENTATIVE IS TO DENY THAT.

15 IT SEEMS TO ME KFX SAYS IT DOES HAVE SUCH
16 INFORMATION, THEY OUGHT TO BE ABLE TO PUT IN THE INFORMATION
17 THEY HAVE. AND THEN IF ARTHREX BELIEVES IT IS INSUFFICIENT IT
18 WOULD BE FERTILE GROUNDS FOR A RULE 50(A) MOTION.

19 THE FOURTH IS A MOTION TO PRECLUDE KFX FROM
20 PRESENTING EVIDENCE OF REEXAMINATION. THE TENTATIVE HERE IS
21 TO DENY THAT MOTION.

22 THE REEXAMINATION DID CONSIDER SOME OF THE PRIOR ART
23 HERE, INCLUDING THE THAL '168 PATENT, FOERSTER '730 PATENT AND
24 STONE '482 PATENT. SO THE REEXAMINATION IS RELEVANT. THE
25 ISSUES OVERLAP TO SOME EXTENT WITH THE PRESENT LITIGATION. I

AUGUST 9, 2013

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1 THE COURT: WELL, FOR EXAMPLE, IT SEEMS TO ME THAT
2 UNDERLYING INFORMATION AN EXPERT CAN TESTIFY ABOUT. WHAT
3 SEEMED PROBLEMATIC TO ME WAS THE EXPERT GOING TO THE FINAL
4 STAGE AND SAYING BASED ON ALL OF THIS INFORMATION IT IS MY
5 OPINION THAT ARTHREX ACTIVELY AND KNOWINGLY AIDED AND ABETTED
6 IN DIRECT INFRINGEMENT.

7 THAT IS LIKE AN EXPERT TESTIFYING, PERHAPS IN AN
8 UNFAIR COMPETITION CASE, THAT BASED ON THE FACTS OF THE
9 COMPETING BUSINESSES AND THE VARIOUS FACTORS, THEY CAN TESTIFY
10 TO THAT. BUT WHAT THEY OUGHT NOT BE ABLE TO TESTIFY TO IS
11 BASED ON ALL OF THAT INFORMATION IT IS MY OPINION AS AN EXPERT
12 THAT THE DEFENDANT COMMITTED OUTRIGHT FRAUD OR IT WAS TOTALLY
13 UNFAIR BUSINESS PRACTICE.

14 BECAUSE THAT DOESN'T ASSIST THE JURY, THAT IS SIMPLY
15 THE EXPERT TELLING THE JURY HOW THEY OUGHT TO VOTE.

16 SO THAT WAS THE CONCERN I HAD WITH THESE ULTIMATE
17 OPINIONS.

18 IT SEEMED TO ME THAT THERE WAS A LOT OF AREA FOR
19 APPROPRIATE TESTIMONY THAT WOULD ASSIST THE TRIER OF FACT, BUT
20 NOT THE ULTIMATE CONCLUSION.

21 MR. JENNINGS: SO THE VIDEOS AND WEBSITES OF ARTHREX
22 MATERIALS THAT INDUCE THE SURGEONS TO THEN DO THE PROCEDURE
23 THAT INFRINGES THE PATENT, AS THE EXPERT WILL EXPLAIN. BUT
24 JUST NOT TO ULTIMATELY SAY WHAT ARTHREX'S SUBJECTIVE INTENT
25 MAY HAVE BEEN.

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1 THINK IT IS FAIR EVIDENCE FOR THE JURY TO CONSIDER. THERE ARE
2 MANY CASES CONSISTENT WITH THAT PROPOSITION. AND THAT THE
3 ISSUES IDENTIFIED BY ARTHREX WOULD BE FERTILE GROUND FOR
4 CROSS-EXAMINATION.

5 I THINK THAT WOULD GO TO WEIGHT RATHER THAN TO
6 ADMISSIBILITY; FOR EXAMPLE, POINTING OUT THAT THE REEXAM WAS
7 EX PARTE WITHOUT THE BENEFIT OF THE COURT'S MARKMAN RULING
8 HERE, WITHOUT LIVE TESTIMONY FROM VARIOUS PERCIPIENT AND
9 EXPERT WITNESSES ON INVALIDITY, PRIOR ART AND THE LIKE.

10 LET'S START WITH MR. JENNINGS. ANY ARGUMENT?

11 MR. JENNINGS: YES, YOUR HONOR.

12 ON THE FIRST MOTION IN LIMINE WITH RESPECT TO DR.

13 TICKER'S OPINION, INFRINGEMENT IS ACTUALLY A QUESTION OF FACT
14 FOR THE JURY. AND AS THE FEDERAL CIRCUIT EXPLAINED IN THE
15 LUCENT CASE, INTENT TO INDUCE INFRINGEMENT IS GOING TO BE
16 FOUND FROM THE CIRCUMSTANTIAL EVIDENCE OF, YOU KNOW, WHAT IS
17 THE DEFENDANT DOING OUT IN THE MARKETPLACE. AND HERE IT IS
18 PROMOTING A SURGICAL TECHNIQUE WITH TECHNIQUE GUIDES, SHOWING
19 VIDEOS THAT ARE DISCERNIBLE BY SURGEONS -- NOT YOU OR I WHEN
20 WE LOOK AT THESE THINGS.

21 I THINK IT IS VERY RIGHT FOR AN EXPERT TO LOOK AT
22 THAT AND SAY WHAT DOES THIS CIRCUMSTANTIAL EVIDENCE INDICATE.
23 AND IT IS A FACT ISSUE, NOT AN ULTIMATE LEGAL CONCLUSION.

24 SO I AM NOT -- I WASN'T QUITE TOTALLY CLEAR AS THE
25 LINE THE COURT WAS DRAWING IN THAT RULING.

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1 THE COURT: THAT'S A FAIR WAY TO CHARACTERIZE IT.

2 THEN ALSO FOR THE EXPERT NOT TO GIVE THE ULTIMATE
3 OPINION. AND THAT IS, BASED ON THAT INFORMATION IT IS HIS
4 OPINION THAT ARTHREX ENGAGED IN DIRECT INFRINGEMENT.

5 MR. JENNINGS: OR INDUCED INFRINGEMENT.

6 THE COURT: INDUCED INFRINGEMENT. RIGHT.

7 SO IT IS HARD TO ARTICULATE, AND IT IS A LINE THAT
8 IS OFTEN FUZZY. BUT I THINK THE AREA TO WATCH IS THE ULTIMATE
9 OPINION.

10 SO I WILL JUST ASK COUNSEL TO WORK WITH THEIR
11 WITNESS IN THAT REGARD.

12 AND THEN OBVIOUSLY, AT THE TIME OF TRIAL, IF MR.
13 DICKERSON BELIEVES THE EXPERT IS CROSSING THE LINE WE CAN
14 ADDRESS THAT BY WAY OF AN OBJECTION AT THAT TIME.

15 MR. JENNINGS: I UNDERSTAND THE COURT'S RULING. OF
16 COURSE IT WOULD APPLY TO THEIR EXPERT NOT OPINING THAT THEY
17 DON'T INDUCE INFRINGEMENT.

18 THE COURT: RIGHT. EXACTLY.

19 MR. JENNINGS: THE CONCLUSION.

20 THEN AS TO NO. 2, I JUST HAD A QUESTION FOR THE
21 COURT.

22 WHEN WE REFER TO THE FACT THAT A ROYALTY WAS
23 DETERMINED AT 16 PERCENT IN THE OTHER CASE, CAN WE MENTION
24 THAT IT WAS ARTHREX AND A COMPETITOR, AND THAT IT INVOLVED THE
25 PUSHLOCK PRODUCT AT ISSUE HERE?

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1 THE COURT: YES. I THINK THAT IS ALL FAIR.

2 MR. JENNINGS: OKAY.

3 THE COURT: WHAT MAKES IT UNFAIRLY PREJUDICIAL IS IF
4 THE EXPERT TRIES TO DOG-PILE ON THAT BY SAYING OH, BY THE WAY,
5 A JURY FOUND THAT AND THEY ARRIVED AT A VERDICT.

6 THAT CREATES PROBLEMS.

7 BUT WHAT I THINK IS FAIR IS THAT THAT RATE WAS
8 ARRIVED AT IN A CONSIDERED MANNER IN A RELATED ISSUE. AND SO
9 I THINK IT IS FAIR FOR AN EXPERT TO USE THAT AS A BASIS FOR
10 HIS OPINION ON REASONABLE ROYALTY RATE.

11 THEN THE QUESTION IS HOW MUCH OF THAT INFORMATION
12 CAN HE SHARE WITH THE JURY BEFORE IT RUNS AFOUL OF 403.

13 MR. JENNINGS: RIGHT. I THINK WE CAN WORK OUT THE
14 LANGUAGE WITH COUNSEL ON THAT ONE.

15 AND I DID HAVE ANOTHER QUESTION ON NO. 2. THE
16 COURT'S TENTATIVE ADDRESSED THE DETAIL THAT WAS RAISED IN THE
17 MOTION. WE RAISED IN RESPONSE ANOTHER DETAIL ABOUT THAT CASE
18 THAT SAID YOU CAN'T EXCLUDE THE WHOLE CASE. THERE WAS A
19 RULING IN THAT CASE REGARDING THE PUSHLOCK BEING A TWO-PIECE
20 ANCHOR.

21 THE COURT: YES.

22 MR. JENNINGS: AND AS I UNDERSTAND IT, THEY WILL
23 HAVE THEIR WITNESSES, MR. JOHN SCHMIEDING, THEIR IN-HOUSE
24 COUNSEL, I BELIEVE, WILL TESTIFY ABOUT THEIR GOOD FAITH BELIEF
25 THAT THEY DON'T INFRINGE IN THIS CASE. AND ONE OF THE BASES

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1 ON THESE PATENTS ON THESE CLAIM TERMS ON THESE CLAIM
2 CONSTRUCTIONS, THAT THIS IS WHAT A JUDGE SAID OVER HERE? I
3 FRANKLY CAN'T THINK OF ANYTHING THAT HAS LESS RELEVANCE AND
4 MORE OPPORTUNITY FOR PREJUDICE.

5 LET ME REFER YOUR HONOR TO THE CASE MENDENHALL
6 VERSUS CEDARRAPIDS. FEDERAL CIRCUIT CASE. 5 FED.3RD 1557 AND
7 THE MOST RELEVANT DISCUSSION IS AT 1573 TO 74.

8 AND THE ISSUE THERE WAS WHETHER OR NOT, IN THE
9 SUBSEQUENT CASE, THEY COULD READ OR RELY ON A DECISION BY A
10 JUDGE IN ANOTHER CASE, A PRIOR CASE, INVOLVING THE SAME PATENT
11 REGARDING VALIDITY.

12 AND HERE IS WHAT FEDERAL CIRCUIT SAID: RESPECTING
13 THE FACTUAL ISSUES, THE JURY SHOULD BE NO MORE GUIDED TO ITS
14 FACTUAL DETERMINATIONS BY JUDGE HULL THAN BY THE DISTRICT
15 COURT. SUCH IMPROPER INFLUENCE IS NOT TOLERATED. THE
16 DISTRICT COURT STATED PLAINTIFFS SOUGHT TO HAVE DONE BY JUDGE
17 HULL WHAT THE DISTRICT COURT COULD NOT LEGALLY DO -- INFLUENCE
18 THE JURY'S FACT FINDING MISSION.

19 JURORS, WITH ALL -- FOR GOOD REASON, RESPECT JUDGES.
20 JUDGES SIT UP THERE. I MEAN, I REMEMBER IN MY LAW SCHOOL THE
21 FIRST TIME A PROFESSOR SUGGESTED THAT A JUDGE MIGHT HAVE
22 GOTTEN IT WRONG, WE WERE ALL, LIKE, REALLY? HOW COULD THAT
23 HAPPEN?

24 THAT IS THE SORT OF MINDSET THAT WE HAVE IN THE
25 JURORS.

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1 DEPENDS UPON THAT ANCHOR BEING A ONE-PIECE ANCHOR.

2 THE COURT: YES. AND THANK YOU FOR MENTIONING THAT.
3 I LOST THAT IN MY TENTATIVE. I THINK THAT IS A FAIR AREA TO
4 USE ON CROSS-EXAMINATION.

5 SO IF AN EXPERT OR A PERCIPIENT WITNESS, WHEREVER IT
6 COMES UP WHERE IT MAY BE RELEVANT, IT SEEMS TO ME IT WOULD BE
7 FAIR ON CROSS TO POINT OUT THAT ANOTHER COURT MADE THAT
8 FINDING, WHICH IS ARGUABLY INCONSISTENT WITH ARTHREX' POSITION
9 HERE. SO IT SEEMS TO ME THAT IS A FAIR AREA OF
10 CROSS-EXAMINATION.

11 MR. JENNINGS: THANK YOU, YOUR HONOR.

12 THE COURT: ANYTHING ELSE, WHILE YOU ARE ADDRESSING
13 THESE, ON 3 OR 4?

14 MR. JENNINGS: NO, YOUR HONOR.

15 THE COURT: OKAY.

16 MR. DICKERSON.

17 MR. DICKERSON: YES, YOUR HONOR.

18 LET ME START WITH NO. 2, BECAUSE FRANKLY I THINK
19 THAT IS THE MOST EGREGIOUS ONE, PARTICULARLY THE SECOND PART
20 ABOUT THIS RULING FROM THE PREVIOUS JUDGE AND MOTION FOR
21 SUMMARY JUDGMENT IN 2007. DIFFERENT PARTIES. DIFFERENT
22 PATENT. DIFFERENT PRODUCT, THE PRODUCT HAS CHANGED SINCE
23 THEN. DIFFERENT CLAIM TERM.

24 TO ALLOW THEM, EVEN IN CROSS-EXAMINATION OF ONE OF
25 OUR EXPERTS WHO WAS OPINING IN THIS CASE BETWEEN THESE PARTIES

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1 WHAT YOU ARE BASICALLY DOING WITH THIS RULING, YOUR
2 HONOR, IS SAYING ONE OF OUR NONINFRINGEMENT POSITIONS, WE JUST
3 HAVE TO IGNORE. WE CANNOT -- WE CANNOT BRING THAT AND HAVE
4 THAT JUDGE'S RULING COME IN IN THAT WAY, YOUR HONOR.

5 THE COURT: I MAY HAVE, THEN, MISAPPREHENDED HOW
6 SIMILAR OR, AS YOU WOULD ARGUE, DISSIMILAR THE TWO SITUATIONS
7 ARE.

8 HOW DO YOU DISTINGUISH THE RULING BY JUDGE MOSMAN
9 AND THE ISSUES IN THAT CASE FROM THE ISSUES IN THIS CASE?

10 MR. DICKERSON: DIFFERENT PATENT. DIFFERENT CLAIM
11 LIMITATION. DIFFERENT PRODUCT, THE PRODUCT HAS CHANGED. ARE
12 WE GOING TO HAVE TO GET INTO THAT? YOU TALK ABOUT A SIDESHOW.
13 IT IS STILL NAMED THE SAME THING, BUT THERE HAS BEEN MATERIAL
14 CHANGES TO THE PRODUCT.

15 SO YOU TALK ABOUT SOMETHING -- WHEN WE ARE DEALING
16 WITH 15 HOURS TO TRY TO DO THIS, TO TRY TO UNRING THAT BELL,
17 ISN'T GOING TO HAPPEN.

18 THE COURT: LET ME INQUIRE OF MR. JENNINGS.

19 HOW DO YOU RESPOND TO THAT ISSUE? IT IS REALLY A
20 403 ISSUE THAT INVOLVES DIFFERENT PATENT, DIFFERENT CLAIM
21 LIMITATIONS AND A PRODUCT THAT HAS NOW CHANGED.

22 MR. JENNINGS: IT IS ON A SIMPLE FACT ISSUE. IT IS,
23 IS THE PUSHLOCK ANCHOR A ONE-PIECE OR TWO-PIECE ANCHOR.

24 THERE WAS AN ARGUMENT MADE ON THEIR OTHER SIDE THAT
25 THE EYELET PORTION WAS NOT PART OF THE ANCHOR. AND THE JUDGE

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Exhibit 11

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

KFX MEDICAL CORPORATION, a
Delaware corporation,

Plaintiff and Counterdefendant,

v.

ARTHREX, INCORPORATED, a
Delaware corporation,

Defendant and Counterclaimant.

Case No. 11cv1698 DMS (BLM)

**KFX'S TRIAL BRIEF
PURSUANT TO LOCAL RULE
16.1(f)(9)(a)**

Trial Date: August 19, 2013
Time: 9:00 A.M.
Courtroom 13A
Honorable Dana M. Sabraw

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Pursuant to Local Rule 16.1(f)(9)(a) and paragraph 7 of the Court's July 19, 2013, Order Regarding Trial [D.I. 138], Plaintiff KFx Medical Corporation ("KFx") submits this trial brief.

I. INTRODUCTION

KFx owns U.S. Patent Nos. 7,585,311 ("the '311 patent"), 8,100,942 ("the '942 patent"), and 8,109,969 ("the '969 patent") (collectively, "the KFx patents"). The KFx patents concern a method of attaching soft tissue, such as a tendon, to bone. The patented methods can be used in a number of applications, but primarily have been used for arthroscopically repairing a torn rotator cuff.

In this trial, KFx will demonstrate that Defendant Arthrex, Inc. ("Arthrex") has willfully infringed claims 1, 20 and 28 of the '311 patent, claims 1 and 18 of the '942 patent, and claims 1 and 3 of the '969 patent by making, selling, offering for sale, and promoting the accused SutureBridge and SpeedBridge surgical procedures. KFx will also establish that it is entitled to a reasonable royalty on Arthrex's sales of the products used in the infringing procedures and a permanent injunction to prevent further infringement. Because Arthrex's infringement was and continues to be willful, the Court should award KFx up to three times the damages awarded at trial, as well as KFx's reasonable attorneys' fees.

II. DISPUTED ISSUES

A. Arthrex Has Willfully Infringed the KFx Patents

Arthrex sells products that are marketed for use in its SutureBridge double-row rotator cuff repair technique and its SpeedBridge knotless double-row footprint reconstruction surgical technique. Performance of either Arthrex's SutureBridge or SpeedBridge procedure directly infringes the asserted claims of the KFx patents. Arthrex willfully infringes the asserted claims of the KFx patents by actively inducing surgeons to perform the SutureBridge and SpeedBridge procedures, thereby infringing the KFx patents.

1 **1. Performance of the SutureBridge and SpeedBridge Technique**
2 **Directly Infringes the Asserted Claims of the KFx Patents**

3 To prove infringement, a patentee must establish by a preponderance of
4 the evidence that every limitation of the patent claim be found in the accused
5 method. *See Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225
6 (Fed. Cir. 2001).

7 At trial, KFx will demonstrate by a preponderance of the evidence that
8 the accused SutureBridge and SpeedBridge procedures directly infringe claims
9 1, 20 and 28 of the '311 patent, claims 1 and 18 of the '942 patent, and claims 1
10 and 3 of the '969 patent. Performance of the SutureBridge and SpeedBridge
11 procedures meets every limitation of the asserted claims of the KFx patents.

12 **a. The '311 Patent**

13 Performance of the SutureBridge and SpeedBridge procedures directly
14 infringes claims 1, 20 and 28 of the '311 patent. KFx will present evidence that
15 each limitation of claim 1 is performed when Arthrex's customers practice the
16 SutureBridge and SpeedBridge procedures as taught by Arthrex. These
17 procedures involve first inserting a first anchor into bone such that it is
18 positioned underneath the soft tissue and that no part of the anchor extends
19 beyond an edge of the soft tissue. Second, a length of suture is passed over the
20 tendon, and third, a second anchor (a PushLock or SwiveLock anchor) is
21 inserted into bone so that it is positioned beyond the edge of the soft tissue and
22 is not underneath the soft tissue. Fourth, the length of suture is tensioned to
23 compress an area of tissue to bone between the edge of soft tissue and the first
24 anchor after the second anchor is inserted. Finally the suture is fixedly secured
25 to the second anchor without tying any knots.

26 Claim 20 incorporates the method of claim 1, but includes two additional
27 anchors (*i.e.*, four total suture anchors—two medial and two lateral) and adds an
28 additional requirement that the suture passing from the second medial anchor to

1 the second lateral anchor crosses over the suture passing from the first medial
2 anchor to the first lateral anchor. Claim 28 also incorporates the method of
3 claim 1, and further requires that the inserting, passing, and fixedly securing
4 steps be conducted arthroscopically. KFx will present evidence to show that the
5 accused procedures perform the additional steps recited in these dependent
6 claims.

7 **b. The '942 Patent**

8 Performance of the SutureBridge and SpeedBridge procedures directly
9 infringes claims 1 and 18 of the '942 patent. KFx will present evidence that
10 each limitation of claim 1 is performed when Arthrex's customers practice the
11 SutureBridge and SpeedBridge procedures as taught by Arthrex. First, a first
12 anchor is inserted into bone such that it is positioned underneath the soft tissue,
13 and second, suture is passed through and over the rotator cuff tissue. Third, a
14 second anchor that has a distal member and a proximal member is inserted into
15 bone at a position beyond an edge of the soft tissue. The second (lateral) anchor
16 in the SutureBridge and SpeedBridge procedures includes a distal member and a
17 proximal member because the PushLock and SwiveLock anchors are two-piece
18 anchors with an eyelet portion (the distal member) and a body portion (the
19 proximal member). Fourth, after inserting the distal member of the second
20 anchor, the length of suture from the first anchor is tensioned to compress an
21 area of tissue to bone between the edge of the soft tissue and the first anchor.
22 Finally, the techniques each include the step of fixedly securing the length of
23 suture at the second anchor position, without tying any knots, by moving the
24 proximal member distally toward the distal member. In the infringing
25 techniques, this is done when the anchor body (proximal member) is screwed or
26 tapped into the bone until it is adjacent to the eyelet portion (distal member).

27 Claim 18 recites the method of claim 1, but includes a second medial
28 anchor, which is referred to as the third anchor in the claim. KFx will present

1 evidence to show that the accused procedures include the additional
2 requirements recited in this claim.

3 **c. The '969 Patent**

4 Performance of the SutureBridge and SpeedBridge procedures directly
5 infringes claims 1 and 3 of the '969 patent. KFx will present evidence that each
6 limitation of claim 1 is performed when Arthrex's customers practice the
7 SutureBridge and SpeedBridge procedures as taught by Arthrex. First, a first
8 anchor is inserted into bone such that it is positioned underneath the soft tissue,
9 and second, suture is passed through and over the rotator cuff tissue. Third, a
10 portion of a second anchor (the distal or eyelet portion of the Pushlock or
11 SwiveLock two-piece anchor) is inserted into bone so that it is positioned
12 beyond the edge of the soft tissue. Fourth, the length of suture is tensioned to
13 compress an area of tissue to bone between the edge of soft tissue and the first
14 anchor after the portion of the second anchor is inserted. Fifth, the techniques
15 each include the step of fixedly securing the length of suture at the second
16 anchor position without tying any knots. Finally, PushLock and SwiveLock
17 anchors each include an anchor tip (the distal eyelet portion of the anchor) and a
18 hollow cylinder (the proximal body portion of the anchor), and the distal eyelet
19 portion includes an aperture through which suture material is threaded prior to
20 insertion of the anchor.¹

21 Claim 3 recited the method of claim 1, but further requires that the anchor
22 tip comprises an anchor inserter attachment member. KFx will present evidence
23 to show that the accused procedures include the additional requirement recited
24 in this claim.

25
26 ¹ KFx also asserted a doctrine of equivalents argument as to the "hollow cylinder"
27 limitation. To simplify the case, however, the parties reached the following agreement. KFx
28 will not present the doctrine of equivalents argument and Arthrex will not contest that the
"hollow cylinder" limitation is met by the accused procedures. In other words, Arthrex will
not challenge that it is met but KFx will not tell the jury that Arthrex has conceded it.

1 **2. Arthrex Actively Induced Infringement of the KFx Patents**

2 Under 35 U.S.C. § 271(b), “[w]hoever actively induces infringement of a
3 patent shall be liable as an infringer.” To establish induced infringement, the
4 patentee must show by a preponderance of the evidence that the defendant acted
5 with specific intent to induce infringement of the patent. *See DSU Med. Corp.*
6 *v. JMS Co., Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (*en banc*). This requires
7 the patentee to prove that the defendant knew of the patent or was willfully
8 blind to its existence, and knew or was willfully blind to the fact that the acts it
9 induced, if taken, would constitute infringement of the patent. *See Commil*
10 *USA, LLC v. Cisco Sys., Inc.*, No. 2012-1042, 2013 WL 3185535, at *3-*4 (Fed.
11 Cir. June 25, 2013). The patentee must also demonstrate that someone directly
12 infringed at least one patent claim. *See Lucent Techs., Inc. v. Gateway, Inc.*,
13 580 F.3d 1301, 1322 (Fed. Cir. 2009).

14 KFx will demonstrate by a preponderance of the evidence that Arthrex’s
15 SutureBridge and SpeedBridge procedures directly infringe the asserted claims
16 of the KFx patents. KFx will also show that Arthrex knew of the KFx patents
17 and acted with specific intent to induce infringement of the KFx patents. For
18 example, at least as early as September 2006, John Schmieding, Arthrex’s in-
19 house counsel, was aware of the KFx patent application that issued as the ’311
20 patent. Arthrex emails from August 2009 prove that Arthrex knew of the ’311
21 patent claims one month before the patent issued, and additional emails from
22 September 2009 prove that Arthrex knew that the patent had issued. Despite
23 this knowledge, Arthrex has provided multiple teaching guides, animations, and
24 surgical videos on its website that demonstrate for surgeons how to perform the
25 SutureBridge and SpeedBridge procedures, procedures which include the steps
26 in the asserted claims of the KFx patents. Moreover, in addition to selling
27 individual components for use in the infringing procedures, Arthrex has also
28 sold kits especially adapted for those procedures. Arthrex has also extensively

1 trained its sales representatives to teach surgeons how to perform the
2 SutureBridge and SpeedBridge procedures and has extensively advertised these
3 procedures. Through this and other evidence, KFx will demonstrate that
4 Arthrex knew or was willfully blind to the knowledge that performance of the
5 SutureBridge and SpeedBridge procedures would infringe the '311 patent.

6 Similarly, when the '942 and '969 patents issued, Arthrex knew or was
7 willfully blind to the fact that the accused SutureBridge and SpeedBridge
8 procedures also infringed these patents because Arthrex was already aware of its
9 infringement of the '311 patent by virtue of this lawsuit.

10 **3. Arthrex's Infringement Is Willful**

11 To establish willful infringement, a patentee must show by clear and
12 convincing evidence that the defendant, with knowledge of the patent, acted
13 despite an objectively high likelihood that its actions constituted infringement.
14 *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (*en banc*).
15 The patentee must also demonstrate that the objectively high risk was either
16 known or so obvious that it should have been known to the defendant. *Id.*

17 KFx will show by clear and convincing evidence that Arthrex knew of the
18 KFx patents and acted despite an objectively high likelihood that its actions
19 constituted infringement. KFx will also demonstrate that the objectively high
20 risk was known or so obvious it should have been known to Arthrex.
21 Notwithstanding Arthrex's knowledge of the risk that the accused procedures
22 infringe the KFx patents, Arthrex has done nothing to change its business
23 practices. Rather, Arthrex continues to violate KFx's intellectual property
24 rights.

25 Although Arthrex obtained legal opinion letters regarding the KFx
26 patents, those opinions were not sought until years after KFx's '311 patent
27 issued and well after KFx filed this lawsuit. KFx will show that these opinion
28 letters were untimely and cannot negate Arthrex's knowledge of the objective

1 high risk of infringement. Moreover, the opinions were so fundamentally
2 flawed that they could not have provided a reasonable basis for Arthrex to
3 conclude that the SutureBridge and SpeedBridge procedures did not infringe the
4 KFx patents or that the patents were invalid.

5 **B. The KFx Patents Are Valid**

6 Patents are presumed to be valid. 35 U.S.C. § 282. To overcome this
7 presumption, the party challenging the validity of a patent must prove facts
8 supporting a determination of invalidity by clear and convincing evidence. *See*
9 *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315 (Fed. Cir. 2002). At
10 trial, Arthrex will not be able to meet its burden of demonstrating invalidity by
11 clear and convincing evidence.

12 **1. The Asserted Claims of the KFx Patents Are Not Anticipated**

13 To establish that a patent is invalid based upon anticipation, the party
14 challenging the validity of the patent must prove by clear and convincing
15 evidence that the claimed inventions are not new. *See* 35 U.S.C. § 282;
16 *TypeRight Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1157 (Fed. Cir.
17 2004). For a claim to be invalid because it is not new, each and every element
18 in the claim must be present *in a single item of prior art*, and arranged or
19 combined in the same way as recited in the claim. *See Net MoneyIN, Inc. v.*
20 *VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (emphasis added).

21 Arthrex cannot meet its burden of proving by clear and convincing
22 evidence that a single item of prior art, *i.e.*, a single prior art procedure or prior
23 art disclosure of a procedure, discloses all elements of the asserted method
24 claims of the KFx patents. Arthrex contends that a collection of items it labels
25 the “ElAttrache/Arthrex work” anticipates the asserted claims of the KFx
26 patents. Yet Arthrex has not—and cannot—identify *a single item of prior art*
27 from within this collection that discloses each and every limitation of the
28 asserted claims with the limitations arranged in the same way as recited in the

1 asserted claims. For example, this work did not include, *inter alia*, the step of
2 tensioning suture after inserting the Bio-Tenodesis screw, or any portion
3 thereof, into bone and also included tying knots over the screw to secure the
4 suture thereto. Moreover, because the Bio-Tenodesis is a single-piece anchor, it
5 cannot meet any of the limitations requiring a two-piece anchor. And much of
6 Arthrex's evidence of the "ElAttrache/Arthrex work" does not constitute prior
7 art or evidence of an item of prior art under any subsection of 35 U.S.C. § 102.

8 **2. The Asserted Claims of the KFx Patents Are Not Obvious**

9 To establish that a patent is invalid as obvious in view of the prior art, the
10 party challenging the validity of the patent must show by clear and convincing
11 evidence that the claimed invention would have been obvious to persons of
12 ordinary skill in the art at the time the invention was made. *See* 35 U.S.C. §
13 103; *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012).
14 Obviousness is a question of law based on underlying factual findings including
15 the scope and content of the prior art, the differences between the claims and the
16 prior art, the level of ordinary skill in the art at the time the invention was made,
17 and "secondary considerations" or "objective evidence" of nonobviousness. *See*
18 *Osram Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 706 (Fed. Cir.
19 2012). Objective evidence of nonobviousness includes evidence of copying,
20 commercial success, praise by others, failure of others, and long-felt need. *See*
21 *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1379 (Fed. Cir. 2012).

22 Arthrex will not be able to prove by clear and convincing evidence that
23 the invention claimed by the KFx patents would have been obvious to a person
24 of ordinary skill in the art at the time the invention was made. For example,
25 Arthrex's alleged prior art does not teach or otherwise suggest the invention
26 recited in the claims of the KFx patents, and there is no reason to combine the
27 various prior art references in the manner Arthrex alleges. The only reasons
28 provided by Arthrex's technical expert, Dr. Jonathan Greenleaf, for combining

1 the prior art references as suggested by Arthrex are (1) that the prior art
2 references are in the same technical field, (2) that they all relate to attaching soft
3 tissue to bone, and (3) that they are pertinent to problems addressed in or the
4 devices disclosed in the specification of the KFx patents. This is insufficient to
5 establish a reason for combining the references in the manner alleged by
6 Arthrex. Moreover, Dr. Greenleaf's third proposed reason to combine – that
7 the KFx patent provides a reason for combining the alleged prior art references
8 – is a legally impermissible reason to combine prior art references. Arthrex
9 cannot provide a reason to combine the alleged prior art references and therefore
10 cannot meet its high burden of proving by clear and convincing evidence that
11 the invention claimed by the KFx patents would have been obvious to a person
12 of ordinary skill in the art at the time the invention was made.

13 Moreover, KFx will present evidence at trial regarding various secondary
14 considerations of non-obviousness, including evidence that the inventions of the
15 KFx patents met a long-felt but unresolved need. KFx will also present
16 evidence that its patented methods have been commercially successful as a
17 result of the patented features. KFx will also show that Arthrex recognized a
18 need for KFx's invention after KFx had made its invention.

19 **3. Claims 1 and 3 of the '969 Patent Are Supported by an**
20 **Adequate Written Description**

21 To establish invalidity for failing to comply with the written description
22 requirement, the party challenging validity must show by clear and convincing
23 evidence that the written description of the invention in the patent is not
24 adequate. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1354 (Fed.
25 Cir. 2010) (*en banc*). The written description requirement is satisfied if a person
26 of ordinary skill in the field of the invention would recognize, from reading the
27 patent specification, that the inventor possessed the subject matter finally
28 claimed in the patent. *See Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665

1 F.3d 1269, 1285 (Fed. Cir. 2012). It is unnecessary to spell out every detail of
 2 the invention in the specification, however, and specific examples are not
 3 required to comply with the written description requirement. *Id.*

4 Arthrex cannot prove by clear and convincing evidence that the written
 5 description of the KFx patents does not adequately describe the invention
 6 recited in claims 1 and 3 of the '969 patent. These claims require an anchor tip
 7 comprising an aperture through which suture is threaded prior to inserting the
 8 anchor into bone. The specification of the '969 patent demonstrates that the
 9 inventors were in possession of a method of attaching soft tissue to bone where
 10 at least one anchor comprises an anchor tip having an aperture through which
 11 suture material is threaded prior to insertion of that anchor.

12 **C. KFx Is Entitled to Damages for Arthrex's Willful Infringement**

13 **1. KFx Is Entitled to a Reasonable Royalty for Arthrex's** 14 **Infringement of the KFx Patents**

15 Once liability for infringement has been established, a patentee is entitled
 16 to damages adequate to compensate for the infringement, which shall be no less
 17 than a reasonable royalty. 35 U.S.C. § 284. A reasonable royalty is determined
 18 based upon a hypothetical negotiation between a willing licensor and a willing
 19 licensee occurring just before infringement began. *See Uniloc USA, Inc. v.*
 20 *Microsoft Corp.*, 632 F.3d 1292, 1312 (Fed. Cir. 2011). An established method
 21 of evaluating the likely outcome of this hypothetical negotiation is to consider
 22 the 15 factors set forth in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F.
 23 Supp. 1116, 1120 (S.D.N.Y. 1970).

24 KFx is entitled to a reasonable royalty on the revenue generated by
 25 Arthrex's sale of the products used in the accused procedures occurring after
 26 September 8, 2009, the issue date of the '311 patent. Based on these sales,
 27 KFx's damages expert, Mr. George Strong, will testify that KFx is entitled to
 28 \$61.6 million of damages for sales through June 2013. This equals 11.7% of

1 Arthrex's revenue from products used in the infringing procedures. KFx will
2 also seek an accounting for damages due to any infringing sales from trial
3 forward, and will seek pre-judgment and post-judgment interest on any damages
4 award.

5 To determine the amount of damages owed to KFx, Mr. Strong first
6 determined the number of accused procedures performed by surgeons using
7 Arthrex's products. Although Arthrex does not formally track the number of
8 those procedures, Arthrex has estimated the number of those procedures at
9 various times in the normal course of its business based upon certain
10 assumptions. Mr. Strong will testify that, using Arthrex's estimates and
11 assumptions, as well as a regression analysis, he determined the anchor sales
12 associated with the infringing procedures. Mr. Strong also determined the
13 profits that Arthrex earned from selling anchors for use in those procedures.

14 Mr. Strong will also rely on Dr. Jonathan Ticker, who is an orthopedic
15 surgeon specializing in shoulder surgery and KFx's medical expert. Dr. Ticker
16 opined regarding the types of procedures that would have been available
17 alternatives had the accused procedures not been available, *i.e.*, "but for" the
18 infringement. Dr. Ticker also opined regarding the frequency with which
19 surgeons would have been expected at the time of the hypothetical negotiation
20 to perform the various alternative procedures, each of which used different
21 numbers and types of anchor. Based on Dr. Ticker's determinations, Mr. Strong
22 calculated the incremental profits that Arthrex earned from selling anchors to be
23 used in the accused procedures instead of the alternative procedures.

24 Mr. Strong will further testify that parties to a hypothetical negotiation
25 would have determined a reasonable royalty based on that incremental profit.
26 Mr. Strong will testify that, after considering the *Georgia Pacific* factors, an
27 equal division of the incremental profits is the proper measure of a reasonable
28 royalty in this case.

2. Enhancement of Damages

Upon a finding of infringement and assessment of damages against the infringer, “the court may increase the damages up to three times the amount found or assessed.” 35 U.S.C. § 284. The decision to award such enhanced damages may be based on willful infringement or bad faith. *See Seagate*, 497 F.3d at 1368 (citing *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 923 F.2d 1576, 1578 (Fed. Cir. 1991)). Based on Arthrex’s willful infringement of the KFx patents, KFx is entitled to up to three times the amount of damages awarded.

3. Arthrex Should Pay KFx’s Attorneys’ Fees

In exceptional cases, the court may award reasonable royalties to the prevailing party. 35 U.S.C. § 285. A defendant’s willful infringement justifies an award of reasonable attorneys’ fees. *See Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 37 (Fed. Cir. 2012). Based on Arthrex’s willful infringement of the KFx patents, the Court should deem this case exceptional and award KFx its attorneys’ fees.

D. Arthrex Should Be Permanently Enjoined From Continuing To Infringe The KFx Patents

After establishing infringement of a valid patent, a court may grant an injunction in accordance with the principles of equity to prevent continued infringement. 35 U.S.C. § 283. To obtain a permanent injunction, the plaintiff must demonstrate:

- (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).

KFx will demonstrate that it has suffered irreparable injury because of Arthrex's willful infringement of the KFx patents. KFx will also show that remedies at law, such as monetary damages, are inadequate to compensate KFx for the injury suffered as a result of Arthrex's willful infringement of the KFx patents. Additionally, KFx will show that, in considering the balance of hardships between KFx and Arthrex, a remedy in equity is warranted. Finally, KFx will demonstrate that the public interest would not be disserved by permanently enjoining Arthrex from infringing the KFx patents.

III. PROCEDURAL ISSUES

KFx is not currently aware of any procedural issues that require resolution by the Court.

IV. EVIDENTIARY ISSUES

The parties have raised a number of objections to one another's exhibits and deposition designations. However, one exhibit that Arthrex only recently added to its exhibit list, DX 5987, raises an important evidentiary issue that should be addressed prior to trial. Because Arthrex only added DX 5987 to its exhibit list on August 9, 2013, the day the Court heard argument on motions *in limine*, KFx was not aware that Arthrex intended to use the exhibit when KFx prepared its motions *in limine*. Nevertheless, DX 5987 should be excluded under Rules 402 and 403, and Arthrex should be precluded from making any reference to the exhibit at trial.²

A. Background – Arthrex's Method Patent (DX 5987)

DX 5987 is a copy of U.S. Patent No. 8,012,174, a patent that Arthrex obtained on the specific surgical procedures at issue in this case. Appendix 1 (DX 5987). The specification of the '174 patent expressly refers to and

² DX 5987 is an Arthrex patent. Arthrex also added the patent's file history (DX 5988) and publication (DX 5993) to its exhibit list on the same day, August 9, 2013. These two exhibits should be excluded for the same reasons DX 5987 should be excluded.

describes Arthrex's PushLock and SwiveLock anchors, *id.* at col. 4, lines 8-15 and 54-59, and the claims of the '174 patent are limited to methods using anchors with certain specific features of the PushLock and SwiveLock, *id.* at cols. 6-10. For example, the claims of the '174 patent all require a "cannulated interference device." *Id.*

The provisional patent application that led to the '174 patent was filed on February 1, 2006, sixteen months after KFx filed the September 17, 2004 provisional application that led to the asserted KFx patents. *Id.* KFx's '311 patent is therefore prior art to the '174 patent and, in fact, the publication of KFx's June 1, 2005 patent application is listed among the "References Cited" on the front page of the '174 patent. *Id.*

B. Arthrex's Method Patent Is Legally Irrelevant And Should Be Excluded Under Rule 402

The fact that Arthrex has a patent on a specific implementation of KFx's patented surgical method – one using the specific anchors marketed by Arthrex – is *no defense* to Arthrex's infringement of the KFx patents. As the Federal Circuit explained long ago, "where [a] defendant has appropriated the material features of the patent in suit, infringement will be found even when those features have been supplemented and modified to such an extent that the defendant may be entitled to a patent for the improvement." *Atlas Powder Co. v. E. I. Du Pont De Mours & Co.*, 750 F.2d 1569, 1580 (Fed. Cir. 1984) (quotation marks omitted); *see also Bio-Technology Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1559 (Fed. Cir. 1996) ("The existence of one's own patent does not constitute a defense to infringement of someone else's patent."). This is because a patent is not a determination by the Patent Office that the patent owner has the right to practice his invention; rather, a patent only confers the right to exclude others from using the invention. *See Atlas*, 750 F.2d at 1580-81 (citing *Herman v. Youngstown Car Mfg. Co.*, 191 F. 579 (6th Cir. 1911)).

Because Arthrex's patent on the infringing surgical procedures is no defense to infringement, that patent is irrelevant to any issue in the case and should be excluded. *See Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1324 (Fed. Cir. 2000) (affirming the exclusion of the defendant's patent); *Bio-Technology*, 750 F.2d at 1559 (that the defendant had patented its specific method was "irrelevant"); *Advanced Respiratory, Inc. v. Electromed, Inc.*, 2003 WL 25674810, *1 (D. Minn. June 27, 2003) (excluding the defendants' patent because "issuance of the '749 patent is not relevant to the infringement issue").³

C. Arthrex Should Be Precluded Under Rule 403 From Introducing Or Referring To Its Irrelevant Method Patent

Arthrex's method patent should also be excluded because it would cause jury confusion and unfair prejudice to KFx, and because it would waste time and distract the jury. Jurors unfamiliar with the law inevitably conclude, contrary to black-letter law, that the Patent Office would not have granted a defendant its own patent unless the defendant was entitled to practice that patent. In this case, the law is counter-intuitive. Thus, even well-instructed jurors tend to conclude that a defendant with a patent cannot infringe other patents, especially the patents considered by the Patent Office. KFx's '311 patent publication was considered by the Patent Office during the prosecution of Arthrex's application, making it highly likely that jurors would become confused and improperly rely on DX 5987 as proof of noninfringement. Such jury confusion would unfairly prejudice KFx.

³ The courts have carved out one narrow exception to the rule that a defendant's patent on the accused product or method is irrelevant. Specifically, a defendant's patent can sometimes be relevant to establishing that the differences between the accused product or method and the claimed invention are not insubstantial and therefore that the accused product or method is not equivalent to the claimed invention under the doctrine of equivalents. However, that exception is inapplicable here. KFx has dropped its claim of infringement under the doctrine of equivalents pursuant to an agreement between the parties. The jury verdict form and jury instructions filed today by KFx reflect this streamlining of the case.

Moreover, introducing DX 5987 would distract the jury from the real issues in the case and result in much wasted time. Before the Court set time limits of fifteen hours per side, KFx expected to address DX 5987, the issued ‘174 patent, in the course of addressing the patent application that led to the ‘174 patent. The patent *application* is relevant because, as explained in KFx’s opposition to Arthrex’s summary judgment motion, Arthrex originally tried to obtain a broad patent directed to KFx’s invention long after KFx had filed its own patent application. Arthrex’s broad patent application therefore constitutes praise for KFx’s patented invention, a “secondary consideration” which indicates that KFx’s invention is not obvious. However, because KFx’s application was filed first and was prior art to Arthrex’s application, Arthrex was required to narrow its claims to cover only an alleged improvement to the KFx procedure. The narrow patent that resulted, DX 5987, is not relevant to any issue in the case. Only if KFx relied on the Arthrex patent application could the resulting issued patent arguably be admissible for completeness.

After the Court set time limits for trial, KFx recognized that it would not have time to explain to the jury the relevance of Arthrex’s broad patent application *and* ensure that the jury understood that the narrower issued patent was not evidence of noninfringement. Accordingly, KFx will not introduce or refer to the patent application. The issued patent is therefore not necessary for completeness and thus has no relevance to any issue in the case. If Arthrex is permitted to introduce or discuss this irrelevant patent, however, KFx will be forced to waste valuable time explaining the patent’s file history, establishing the narrow scope of its claims, and ensuring that the jury understands that the patent is not proof of noninfringement.

Because of the risk of jury confusion and unfair prejudice to KFx, as well as the certainty of wasted time and distraction of the jury, the Court should preclude Arthrex from introducing or referring to DX 5987. *See Glaros v. H.H.*

1 *Robertson Co.*, 797 F.2d 1564, 1572-73 (Fed. Cir. 1986) (“Introduction of [the
2 defendant’s patent and other evidence] would have injected frolics and detours
3 and would have required introduction of counter-evidence, all likely to create
4 side issues that would have unduly distracted the jury from the main issues.”);
5 *Advanced Respiratory*, 2003 WL 25674810 at *1 (“Aside from the great
6 confusion that this would cause with the jury, it would also misdirect the jury’s
7 attention from the real issue of the case.”); *Advanced Cardiovascular Sys., Inc.*
8 *v. Medtronic, Inc.*, 2000 WL 34334583, *6 (N.D. Cal. Mar. 31, 2000)
9 (“presenting evidence to the jury that the [accused device] was covered by
10 patents risked misleading the jury...”).

11 In sum, pursuant to Rules 402 and 403 of the Federal Rules Of Evidence,
12 Arthrex should be precluded from introducing or referring to DX 5987.

13
14 Respectfully submitted,

15
16 KNOBBE, MARTENS, OLSON & BEAR, LLP
17

18 Dated: August 12, 2013

By: s/ Joseph F. Jennings _____

19 Joseph F. Jennings
20 Brian Horne
21 Sean M. Murray
22 Sarah Lampton
23 Marissa Calcagno

24 Attorneys for Plaintiff
25 KFx Medical Corporation
26
27
28

PROOF OF SERVICE

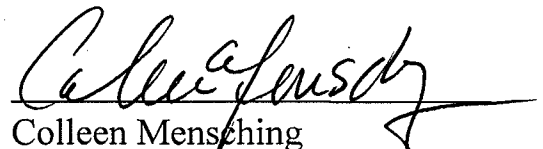
I hereby certify that on August 12, 2013, I caused **PLAINTIFF'S TRIAL BRIEF PURSUANT TO LOCAL RULE 16.1(f)(9)(a)** to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following person(s):

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I certify and declare under penalty of perjury under the laws of the State of California that I am employed in the office of a member of the bar of this Court at whose direction the service was made, and that the forgoing is true and correct.

Executed on August 12, 2013, at San Diego, California.


Colleen Mensching

KFXL.064L
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072213

APPENDIX 1



US008012174B2

(12) **United States Patent**
ElAttrache et al.

(10) **Patent No.:** **US 8,012,174 B2**
 (45) **Date of Patent:** **Sep. 6, 2011**

(54) **METHOD FOR DOUBLE ROW FIXATION OF TENDON TO BONE**

(56) **References Cited**

(75) Inventors: **Neal S. ElAttrache**, Los Angeles, CA (US); **James E. Tibone**, Los Angeles, CA (US)

(73) Assignee: **Arthrex, Inc.**, Naples, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 854 days.

(21) Appl. No.: **11/700,916**

(22) Filed: **Feb. 1, 2007**

(65) **Prior Publication Data**

US 2007/0191849 A1 Aug. 16, 2007

Related U.S. Application Data

(60) Provisional application No. 60/763,915, filed on Feb. 1, 2006.

(51) **Int. Cl.**
A61F 17/04 (2006.01)
A61F 2/08 (2006.01)

(52) **U.S. Cl.** **606/232; 623/13.11**

(58) **Field of Classification Search** **606/224-233; 623/13.11-13.14, 22.36, 23.27**
 See application file for complete search history.

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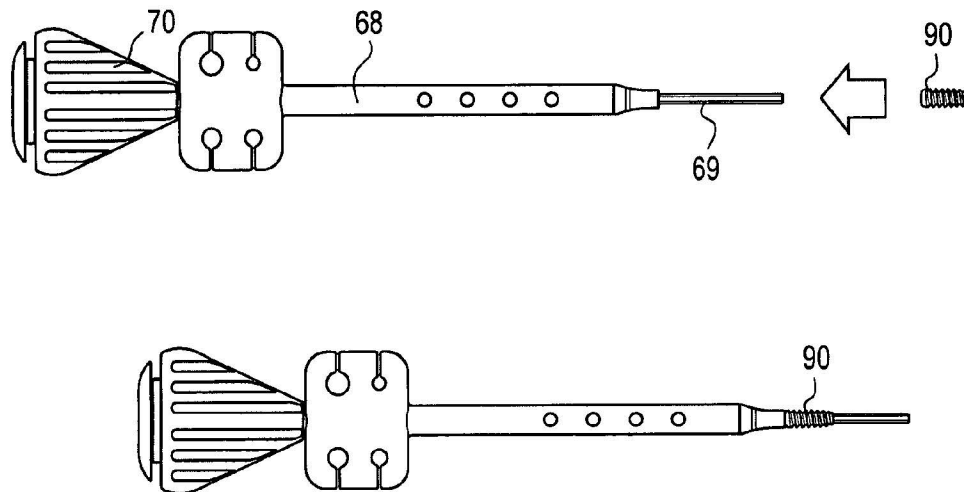
Primary Examiner — Suzette J Gherbi

(74) *Attorney, Agent, or Firm* — Dickstein Shapiro LLP

(57) **ABSTRACT**

A system and method for soft tissue to bone repair employing at least one suture anchor combined with at least one knotless fixation device. The method for soft tissue to bone fixation includes: (i) providing a first medial row constructed with a first plurality of fixation devices, at least one of the first plurality of fixation devices is an anchor; and (ii) providing a second lateral row constructed with a second plurality of fixation devices, at least one of the second plurality of fixation devices is a knotless fixation device, and suture or tape or allograft/biological component extending over the soft tissue and secured in place by the anchors in the first and second medial rows.

29 Claims, 9 Drawing Sheets



Case
 3:11-cv-01658-DMS
 PLAINTIFF
 DEFENDANT'S
Exhibit
5857

U.S. Patent

Sep. 6, 2011

Sheet 1 of 9

US 8,012,174 B2

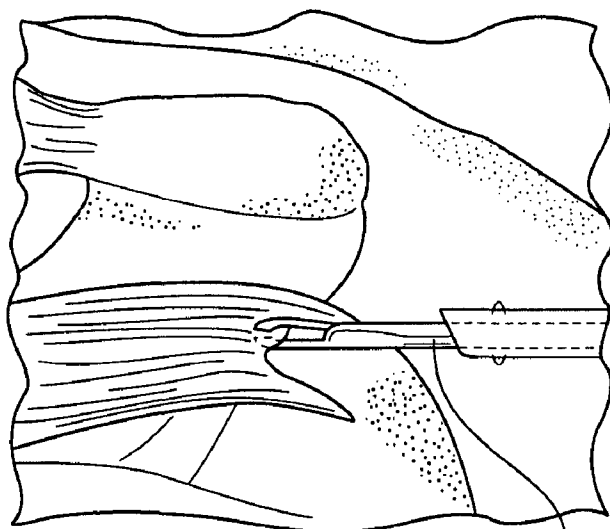


FIG. 1

10

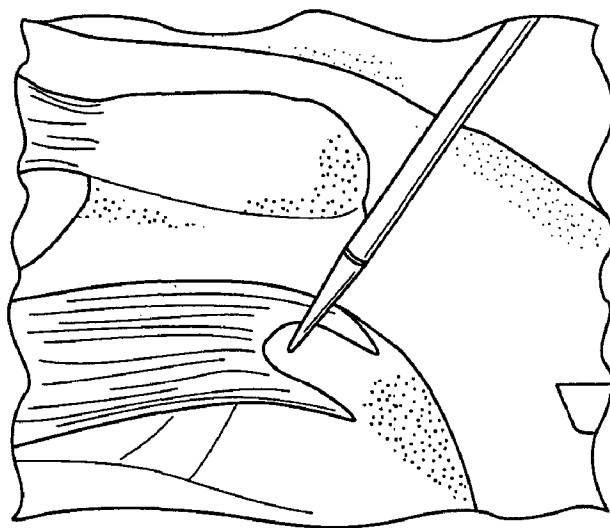


FIG. 2

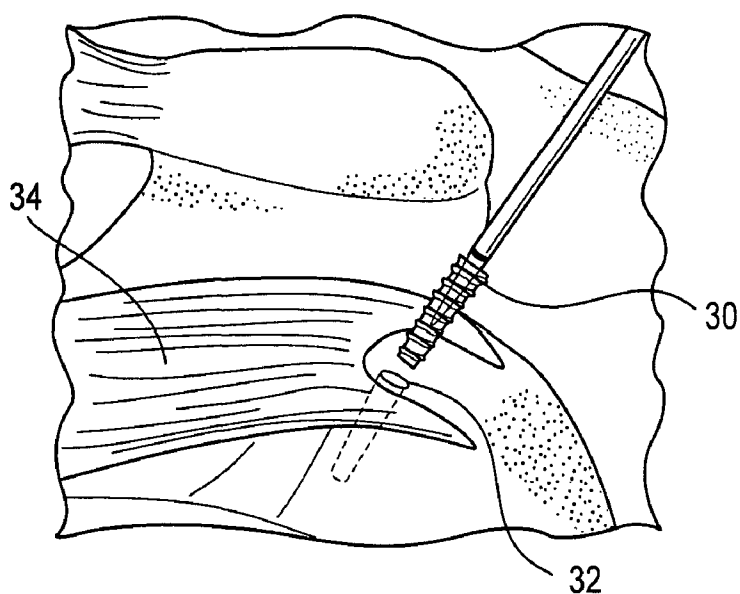


FIG. 3

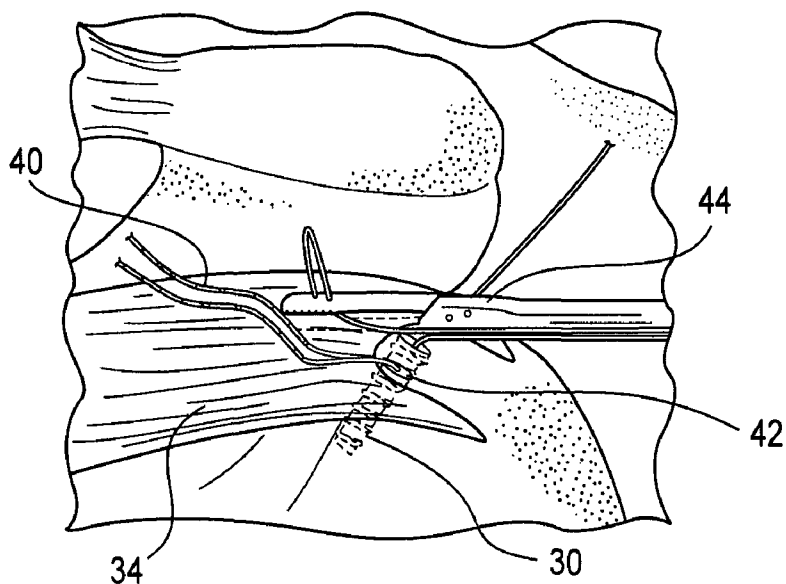


FIG. 4

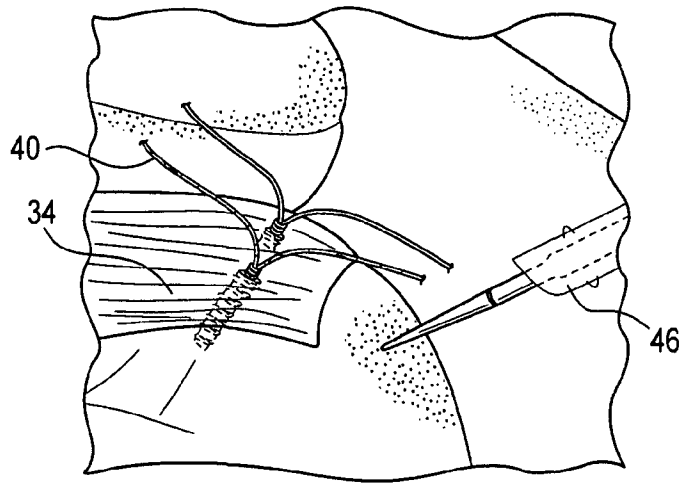


FIG. 5

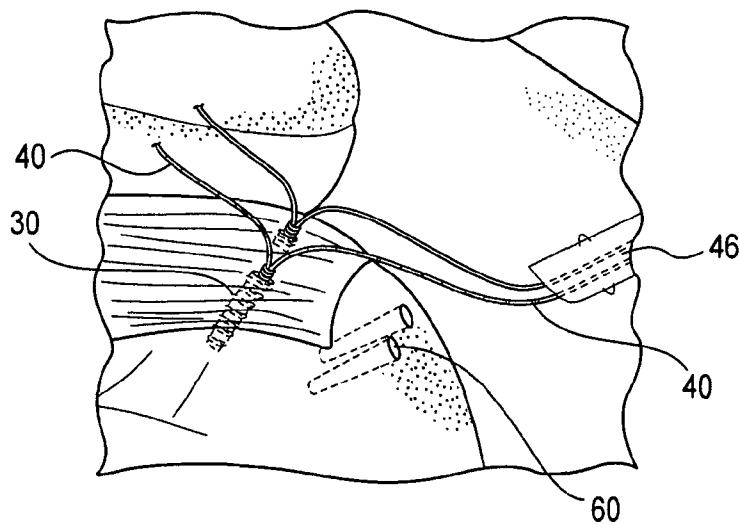


FIG. 6

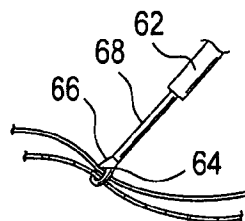


FIG. 6a

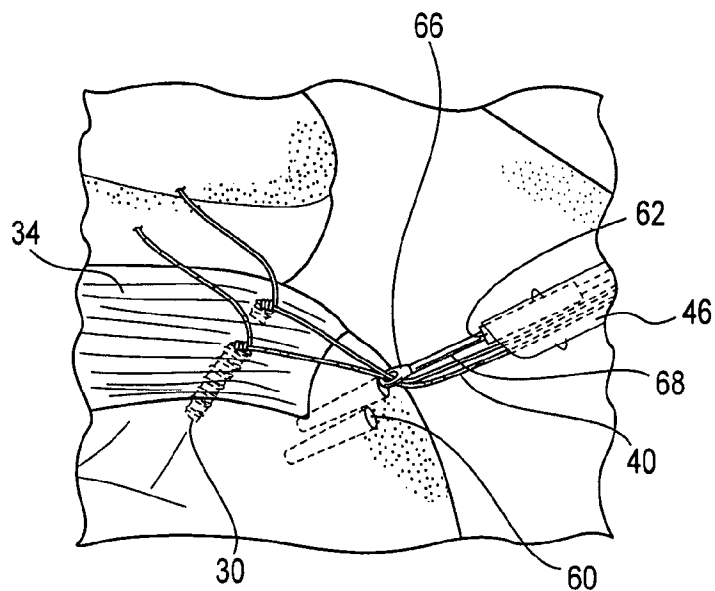


FIG. 7

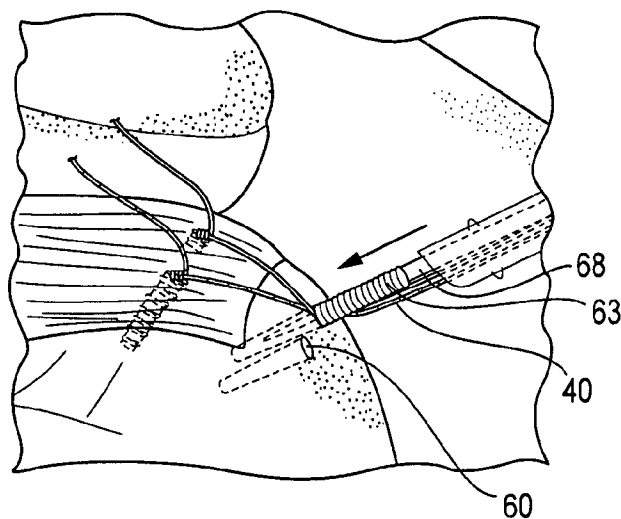


FIG. 8

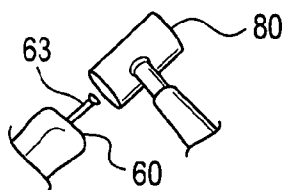


FIG. 8a

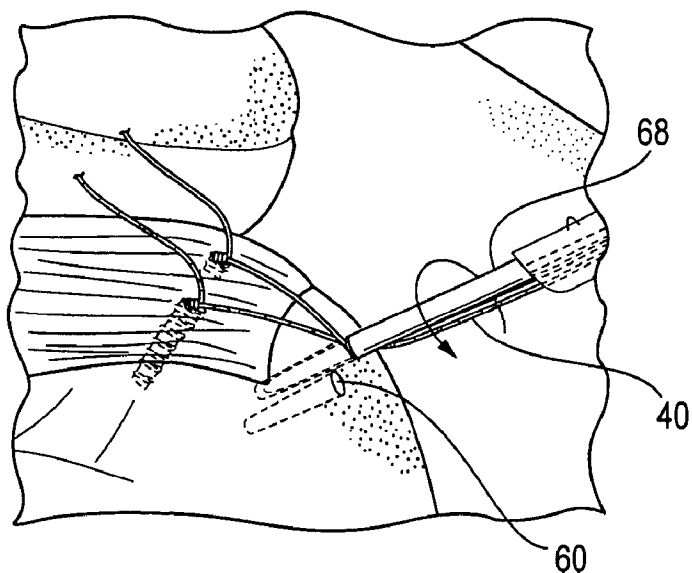


FIG. 9

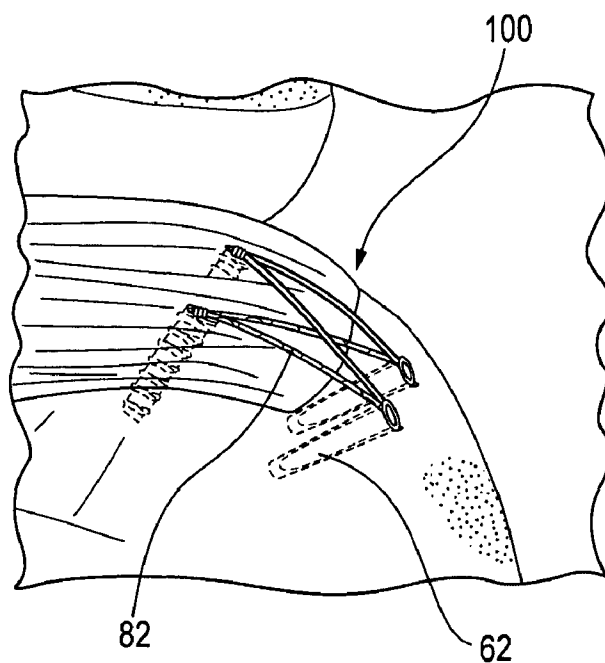


FIG. 10

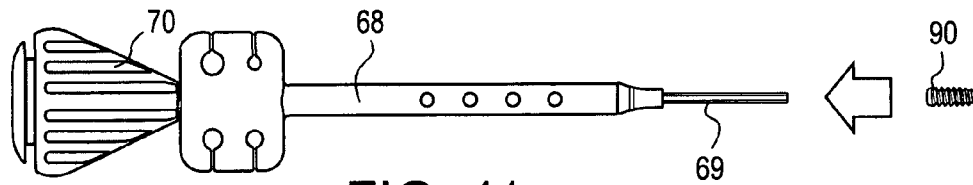


FIG. 11a

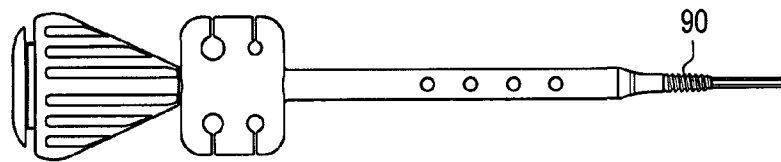


FIG. 11b

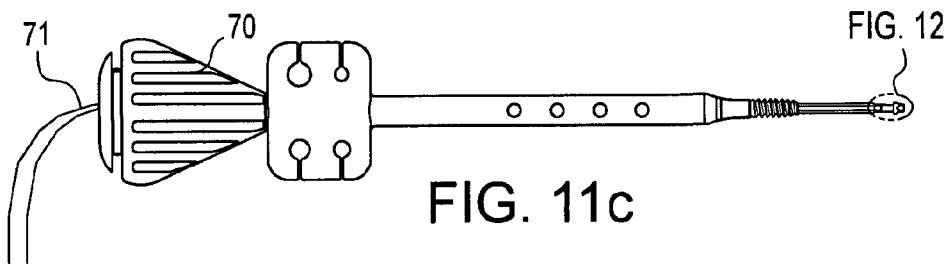


FIG. 11c

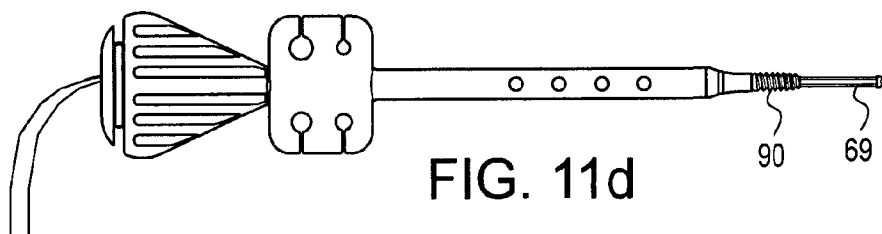


FIG. 11d

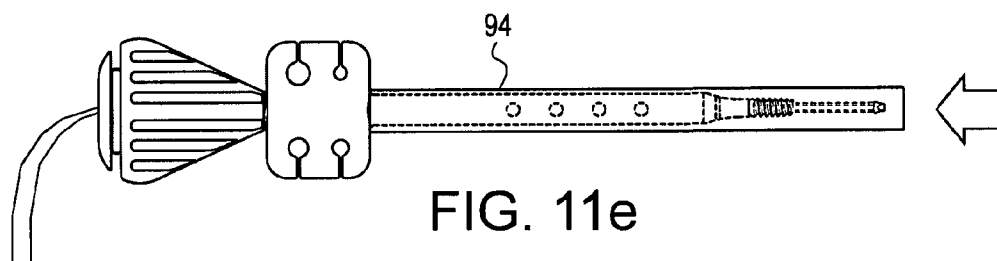


FIG. 11e

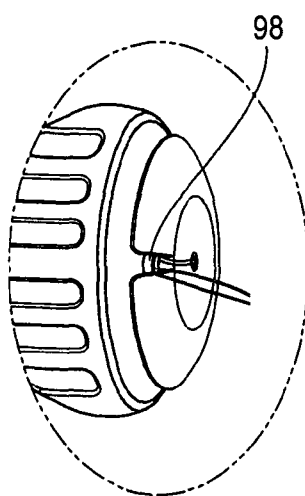
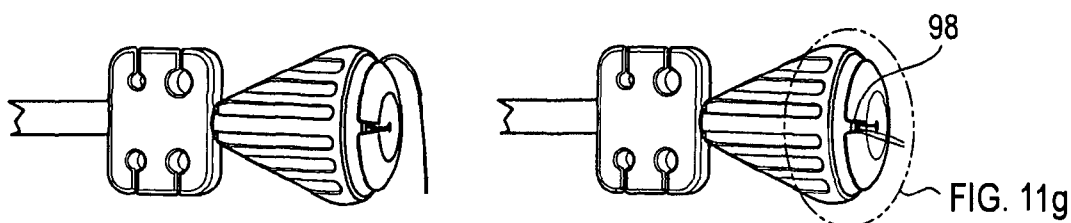


FIG. 11g

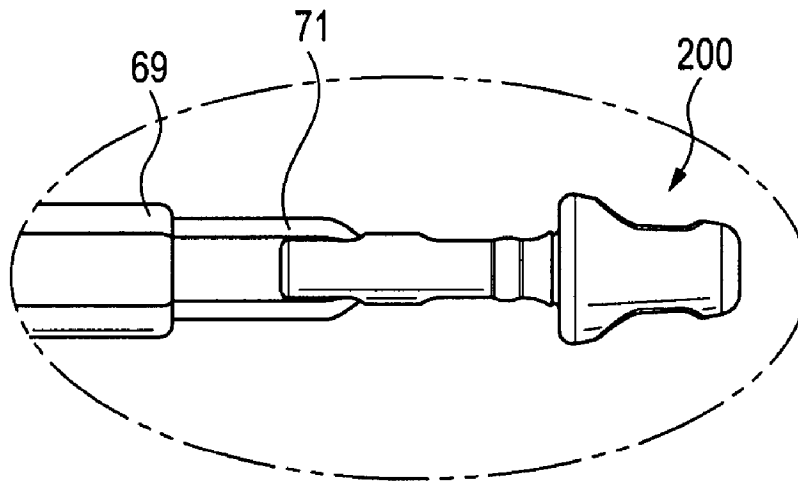


FIG. 12

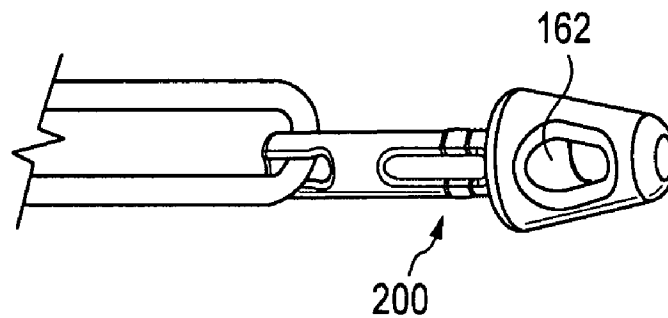


FIG. 13

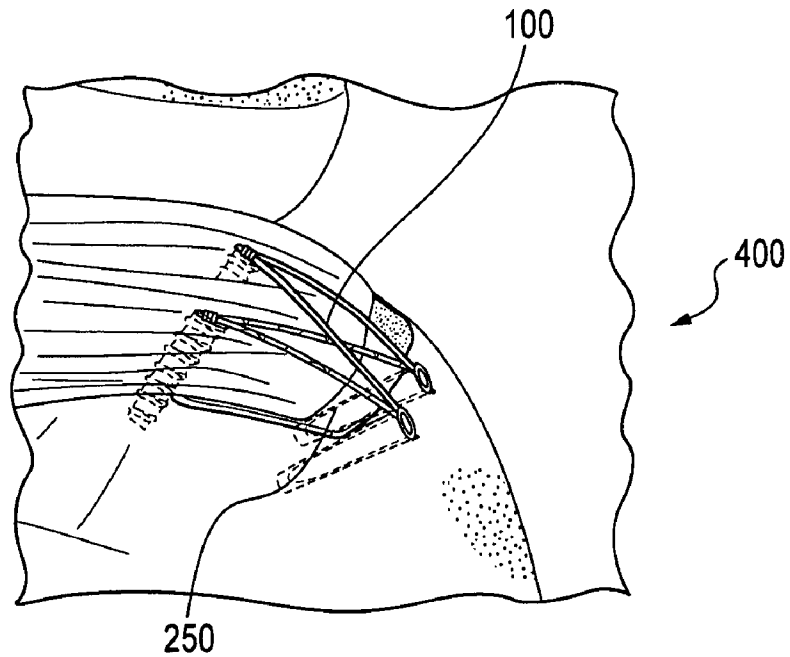


FIG. 14

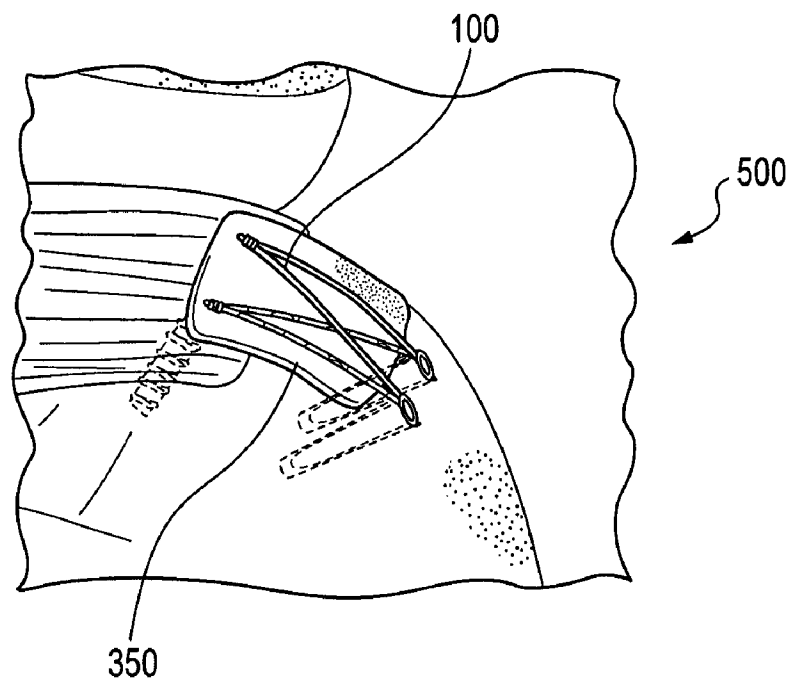


FIG. 15

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**METHOD FOR DOUBLE ROW FIXATION OF
TENDON TO BONE****CROSS-REFERENCE TO RELATED
APPLICATIONS**

This application claims the benefit of U.S. Provisional Application No. 60/763,915, filed Feb. 1, 2006, the entire disclosure of which is incorporated by reference herein.

FIELD OF THE INVENTION

The present invention relates to methods of arthroscopic surgery and, more specifically, to an improved method of attaching tissue to bone, such as rotator cuff repair.

BACKGROUND OF THE INVENTION

When soft tissue tears away from bone, reattachment becomes necessary. Various devices, including sutures, screws, staples, wedges, anchors and plugs have been used in the prior art to secure soft tissue to bone. Surgical methods utilizing suture anchors alone are disadvantageous for reattachment of large areas of detached tissue because they often do not allow good tissue to bone contact.

Reattachment of soft tissue to bone typically requires the surgeon to pass suture material through selected tissue, form a plurality of surgical knots extracorporeally and then move the knots into position adjacent the desired tissue to be sutured. In such procedures, the surgeon must manually tie the knots on the suture strands after the suture is threaded through the selected tissues to be sutured. Knot tying during surgery, particularly arthroscopic surgery, is tedious and time-consuming. There is also a tendency for the knots to deform or collapse as the surgeon manually forces the knots down into the proper position. Also, the suture knots often are exposed to abrasion or cutting by sharp or rough areas along the walls of the bone canal into which anchors are typically inserted to provide fixation of tendon to bone.

Accordingly, a need exists for an improved method for attaching soft tissue to bone which does not require multiple suture knots and which allows the tendon to remain securely in place until the ligaments naturally attach to bone. A method of threading suture through a tendon with maximum suture fixation strength, as well as a method of securing the tendon to bone that allows for accelerated tendon healing to bone are also needed.

BRIEF SUMMARY OF THE INVENTION

The present invention provides a system and method for soft tissue to bone repair employing at least one suture anchor combined with at least one knotless fixation device.

More specifically, the present invention provides a method for tendon to bone fixation which includes: (i) providing a first medial row constructed with a first plurality of fixation devices, at least one of the first plurality of fixation devices being an anchor; (ii) providing a second lateral row constructed with a second plurality of fixation devices, at least one of the second plurality of fixation devices being a knotless fixation device; and (iii) providing a structure comprising an element selected from the group consisting of suture, tape and allograft/biological component, and extending the structure over the soft tissue so that the structure is secured in place by the anchors.

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Other features and advantages of the present invention will become apparent from the following description of the invention, which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view illustrating an initial step of a method of arthroscopic rotator cuff repair according to an exemplary embodiment of the present invention.

FIG. 2 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 1.

FIG. 3 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 2.

FIG. 4 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 3.

FIG. 5 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 4.

FIG. 6 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 5.

FIG. 7 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 6.

FIG. 8 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 7.

FIG. 9 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 8.

FIG. 10 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 9.

FIGS. 11(a)-(g) illustrate various steps of assembling a driver with a swivel knotless fixation device employed during a knotless repair according to the present invention.

FIG. 12 is a first enlarged side view of the swivel anchor implant illustrated in FIGS. 11(a)-(g).

FIG. 13 is a second enlarged side view of the swivel anchor implant of FIG. 12.

FIG. 14 is a side view of the structure of FIG. 1 according to a second exemplary embodiment of arthroscopic rotator cuff repair of the present invention.

FIG. 15 is a side view of the structure of FIG. 1 according to a third exemplary embodiment of arthroscopic rotator cuff repair of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, where like elements are designated by like reference numerals, FIGS. 1 through 15 illustrate systems and methods of attaching a tendon to bone according to the present invention. For exemplary purposes only, the invention will be described below with reference to an arthroscopic rotator cuff repair. However, the invention is not limited to this exemplary embodiment and has applicability to any reattachment of soft tissue to bone.

The methods of the present invention enhance footprint compression and allow for accelerated tendon healing to bone that is achieved with minimal knot tying. The repair consists of a tied medial row constructed with at least one suture anchor combined with knotless lateral fixation using at least one knotless fixation device. Preferably, the repair consists of a tied medial row constructed with two suture anchors (such as two Arthrex 5.5 mm Bio-Corkscrew® FT anchors, for example) combined with knotless lateral fixation using at least one knotless fixation device, preferably at least two knotless fixation devices (such as two Arthrex 3.5 mm PushLock™ anchors, two Arthrex SwivelLock™ anchors, a combination of the PushLock™ and SwivelLock™ anchors, or a combination of at least one of a PushLock™ and SwivelLock™ anchor with another knotless fixation device or with

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other fixation device, among others). The result is a quick, secure and low profile repair with excellent contact between tendon and bone.

FIG. 1 illustrates a side view of a human shoulder of a patient undergoing a rotator cuff repair in accordance with an exemplary embodiment of the present invention. Although this particular embodiment will be illustrated below with reference to FIGS. 1-10 and with reference to only a particular knotless fixation device (such as Arthrex "PushLock" anchor), the invention is not limited to this particular embodiment and contemplates additional embodiments wherein any knotless fixation device may be employed, depending on the characteristics of the repair site and of the particular application.

The patient may be positioned in the beach chair position using the Arthrex Beach Chair Lateral Traction Device or in a lateral decubitus position using the Arthrex 3-Point Shoulder Distraction System. Access to the subacromial space is facilitated with a variety of cannulas.

First, and as illustrated in FIG. 1, the mobility of the tear is assessed using, for example, a tissue grasper 10 such as the Arthrex KingFisher™ Suture Retriever/Tissue Grasper, to determine whether a U or L-shaped component exists. Where large tears extend to the superior aspect of the glenoid, margin convergence suturing is performed to reduce volume and strain on the repair. Subsequently, the length and width of the rotator cuff footprint is assessed and a bleeding bed for enhanced tendon to bone healing may be formed. This may be accomplished with a burr to perform a light dusting of the greater tuberosity, or by using a chondro pick to microfracture the footprint and maximize vascular channels.

FIG. 2 illustrates the preparation of two pilot holes for two suture anchors that will be inserted in the medial row. A punch may be employed adjacent to the articular margin of the humerus and at about 45° angle to form the two pilot holes.

Subsequent to the formation of the pilot holes, and as shown in FIG. 3, a suture anchor 30 is placed in the pre-formed hole 32. As shown in FIG. 4, two suture anchors 30 are placed in the two pre-formed holes 32 in a medial row. These anchors assure full contact of the detached tendon 34 along the medial footprint of the greater tuberosity. In an exemplary embodiment, at least one of the two suture anchors is a fully-threaded bioabsorbable suture anchor having a loop inserted into the suture anchor, and as disclosed and described in U.S. patent application Ser. No. 11/224,060, filed on Sep. 13, 2005 and entitled "Fully-Threaded Bioabsorbable Suture Anchor," the disclosure of which is hereby incorporated by reference in its entirety. In other embodiments, at least one of the two suture anchors may be an Arthrex Biocorkscrew™, disclosed in U.S. Patent Application Publication No. 2004/0106950, the disclosure of which is hereby incorporated by reference in its entirety, having an eyelet and loaded with a single or double strands of sutures.

In an exemplary embodiment, suture anchors 30 have a flexible elongated member 40 (for example, suture 40) preferably attached to a proximal end 42, as illustrated in FIG. 4. One strand of suture 40 from each anchor 30 (preferably opposite colors) is removed. Using a suture retriever instrument 44, one of the four remaining sutures 40 is retrieved through the lateral (or anterolateral) cannula 46 and is passed through the tendon 34 using a suture passer instrument 44. This step is repeated for the three remaining sutures 40 to create a horizontal mattress configuration. When large tears are present, and if desired, all suture strands may be used to obtain additional medial fixation. In this case, the additional strands would be tied and cut.

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Referring now to FIG. 5, the medial row is tied leaving the suture tails 40 uncut. As described below, these suture tails 40 will be draped over the lateral aspect of the tendon 34 and will be held in place with two knotless fixation devices. As also shown in FIGS. 5 and 6, two pilot holes 60 for the knotless fixation devices 62 are formed approximately 5-10 mm distal to the lateral edge of the greater tuberosity using a punch, for example, through the lateral (or anterolateral) cannula 46. In an exemplary embodiment, at least one of the two knotless fixation devices 62 is a fixation device (an Arthrex "PushLock" anchor) as disclosed and described in U.S. Patent Application Publication No. 2004/0093031, the disclosure of which is hereby incorporated by reference in its entirety, or an Arthrex "SwiveLock" anchor as described below with reference to FIGS. 11-13.

As illustrated in FIG. 6, one suture strand 40 from each suture anchor 30 is retrieved through the lateral (or anterolateral) cannula 46. Both suture strands 40 are then threaded through an eyelet 64 of the knotless fixation device 62 (for example, through the eyelet of the PushLock anchor or of the SwiveLock anchor) on the distal end 66 of the driver 68.

Subsequently, and as shown in FIG. 7, the distal tip 66 of the knotless fixation device 62 is brought to the edge of the pilot hole 60 while holding onto the suture tails 40. This will reduce the tendon 34 to its desired position on the footprint. Also, the knot stack from the medial suture anchors 30 is forced to lie flat against the tendon 34 minimizing potential impingement issues from the suture 40.

The driver 68 is then completely advanced into the pilot hole 60 beyond the first laser line, until the anchor body 63 contacts the bone and the tissue tension is evaluated (FIG. 8). If it is determined that the tension is not adequate, the driver 68 can be backed out and the tension readjusted. Alternatively, additional tension may be applied, while leaving the driver 68 in place, by pulling on each suture strand 40 independently. A mallet 80 may be employed to impact the anchor body 63 into the pilot hole 60 until the second laser line is flush with the humerus.

Referring now to FIG. 9, the driver 68 is turned counter-clockwise to disengage the eyelet (within pilot hole 60) from the driver shaft. The sutures 40 are then cut flush using a suture cutter (not shown). The steps described above with reference to FIGS. 6 through 9 are subsequently repeated for the second knotless fixation device 62 (for example, a second PushLock anchor) to obtain the criss-cross suturing arrangement 82 of FIG. 10 having double rows of fixation devices. The criss-cross suturing arrangement 82, together with the two suture anchors 30 combined with knotless lateral fixation using the two knotless fixation devices 62 form exemplary repair system 100 (FIG. 10) of the present invention.

FIGS. 11-13 illustrate exemplary steps of the installation of knotless fixation devices with a swivel anchor implant 200 on driver 68 during a knotless method of attaching tissue to bone according to other embodiments of the present invention. The knotless fixation devices with a swiveling implant 200, are sold by Arthrex, Inc. under the tradename SwiveLock™, and may be used in lieu of the exemplary PushLock anchors described above with reference to the exemplary knotless rotator cuff repair described in FIGS. 1 through 10. The installation technique is similar to the one described above, except that the lateral fixation is accomplished by threading suture through an implant 200 that swivels on the shaft of the driver, and the implant is secured by an anchor that is screwed (by rotating the shaft of the driver), rather than pushed, over the implant.

As shown in FIGS. 11(a)-(f), a driver 68 is used to install the knotless fixation devices with a swiveling implant. Driver

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68 features a thin cannulated rod 69 passing slidably and rotatably through a cannulated driver assembly. The tip of thin cannulated rod 69 is adapted to accept swivel anchor implant 200 within the cannulation at its tip, preferably via a snap fit. Cannulated rod 69 has a hexagonal outer surface for receiving anchor body (i.e., a screw) 90 having a corresponding cannulation.

During installation of the knotless anchor having a swiveling implant 200, the screw 90 is first inserted onto cannulated rod 69 of the driver 68. As shown in FIGS. 11(a) and (b), screw 90 is loaded onto rod 69 and then fully seated on the shaft end of the driver. FIG. 11(c) illustrates the swivel anchor implant 200. Traction sutures 71 extending from the proximal end of the swivel anchor implant 200 are threaded through the cannulation of the driver 68 (FIG. 11(c)). Subsequently, the swivel anchor implant 200 is seated on the driver tip and until advanced until it snaps onto place (FIG. 11(d)). A protective tube 94 (FIG. 11(e)) may be placed over the tip of the assembly for shipping purposes. The traction sutures 71 may be looped around the driver handle, as shown in FIGS. 11(f) and (g), and secured in a cleat 98 to prevent the implant 200 from becoming prematurely detached from the driver.

The knotless fixation devices, whether of the first embodiment (PushLock anchors) or the second embodiment (SwivelLock anchors) advantageously minimize or eliminate the need to tie knots. The use of such anchors also provides secure fixation of the suture construct—the secure suture construct results from the suture being pushed into a pilot hole on the lateral row and held tightly by an anchors.

The sutures employed in the method of the present invention may be formed of any flexible material. In the preferred embodiment, the sutures forming the construct are made of a high strength suture material, such as Arthrex FiberWire suture, which is described in U.S. Pat. No. 6,716,234 to Grafton et al., the disclosure of which is incorporated by reference in its entirety. In additional embodiments, the suture strands may be FiberWire sutures of alternating colors to maximize repair strength, aid in suture management and provide superior tying characteristics.

In another preferred embodiment, any flexible elongated member, such as tape, rather than suture, may be employed, to further improve tissue compression, improve fixation in the anchors, and to further hold collagen or bone marrow aspirate better than suture. Preferably, the tape, such as the high strength suture tape disclosed in U.S. Patent Application Publication No. 2005/0192631, the disclosure of which is incorporated by reference herein, is braided and rectangular-like in cross-section. In another preferred embodiment, an allograft or biological component may be used instead of suture or tape. The allograft or biological component may be comprised of tendon or pericardium, for example, which provides improved tissue repair. In yet additional embodiments, any combination of suture, suture tape, and allograft or biological component may be employed, depending on the characteristics of the specific surgical repair and/or as desired.

According to additional exemplary embodiments of the present invention, the present invention may be further employed in conjunction with allograft or porous collagen material that may be optionally hydrated with bone marrow aspirate. In the exemplary embodiments illustrated in FIGS. 14 and 15, repair systems 400, 500 of the present invention comprise, for example, the repair system 100 (described with reference to FIG. 10) and implant material 250, 350 provided arthroscopically (preferably under the tissue prior or above the tissue) prior to implanting the lateral row of the repair system 100.

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In exemplary embodiments, implant material 250, 350 may be porous collagen material (BioSponge™) or tendon allograft (AlloBridge™) that can be readily hydrated or impregnated with a hydrating solution comprising aspirated bone marrow. The hydrating solution may consist essentially of bone marrow, preferably consisting essentially of autogenous bone marrow. Alternatively, the hydrating solution may comprise additional elements, such as various growth factors such as hyaluronic acid, antiseptics and/or antibiotics and medicine materials, in addition to or in lieu of the bone marrow. The BioSponge™ 250 (FIG. 14) or AlloBridge™ 350 (FIG. 15) impregnated or hydrated with bone marrow can act as carrier of bone marrow at the repair site, the bone marrow promoting a biological response to damaged tissue and reinforcing the repair of such damaged tissue. The implanted material 250, 350 may be provided at various locations of the repair site (for example, above the tissue, under the tissue, or extending from the tissue) depending upon the characteristics of the repair site and of the damaged tissue.

During the surgical repair, the bone marrow aspirate provides a cell suspension that can be readily processed intraoperatively for immediate implantation. According to exemplary embodiments, the bone marrow aspirate may be withdrawn from the iliac crest or may be aspirated from the femur and humerus. Once the bone marrow aspirate is aspirated (with a syringe, for example) from an aspirate region such as the humeral head, the BioSponge™ or AlloBridge™ is hydrated with the bone marrow and then the hydrated BioSponge™ or AlloBridge™ is provided arthroscopically (for example, under the tissue) prior to implanting the lateral row implants of system 100. Alternatively, or additionally, bone marrow aspirate may be injected directly or localized to a repair site, to facilitate healing.

The bodies of the fixation devices of the present invention may be preferably formed of a translucent or transparent polymer material, and are preferably made of bioabsorbable materials such as polyglycolic or polylactic acid polymers.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. Accordingly, it is not intended that the present invention be limited to the illustrated embodiments, but only by the appended claims.

What is claimed as new and desired to be protected by Letters Patent of the United States is:

1. A knotless method of attaching soft tissue to bone, comprising:

providing a first medial row constructed with a first plurality of fixation devices, wherein the at least one of the first plurality of fixation devices is an anchor;

providing a second lateral row constructed with a second plurality of fixation devices, wherein the at least one of the second plurality of fixation devices is a knotless fixation device, the knotless fixation device comprising a cannulated interference device and an implant containing an aperture, the aperture being configured to capture a flexible member; and

passing the flexible member through the soft tissue and over a lateral portion of the soft tissue, the flexible member being attached at one end to the anchor and secured at an opposite end in a hole in bone by the knotless fixation device without tying a knot, wherein the step of passing the flexible member further comprises:

passing the flexible member through the aperture of the implant;

inserting the flexible member and the implant into the hole; and

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advancing the cannulated interference device toward a proximal end of the implant, to engage and lock in the implant with the flexible member in the hole.

2. The method of claim 1, further comprising the formation of a structure of multiple passes of said flexible member over the soft tissue, wherein the structure is held in place by the fixation devices in the first and second rows.

3. The method of claim 2, wherein the flexible member of the structure is comprised of suture.

4. The method of claim 2, wherein the flexible member of the structure is comprised of tape.

5. The method of claim 2, wherein the flexible member of the structure is comprised of an allograft or biological component.

6. The method of claim 2, further comprising the step of providing an implant material adjacent to the structure of multiple passes.

7. The method of claim 6, wherein the step of providing an implant material further comprises:

providing aspirate bone marrow;

providing a material to be implanted in the vicinity of a repair site defined by at least the structure of multiple passes;

hydrating the material with aspirate bone marrow to form the implant material; and

securing the implant material at the repair site.

8. The method of claim 6, wherein the implant material is selected from the group consisting of collagen, allograft and bone marrow.

9. The method of claim 8, wherein the implant material is porous collagen impregnated with autogenous bone marrow.

10. The method of claim 8, wherein the implant material is tendon allograft impregnated with autogenous bone marrow.

11. A knotless method of attaching soft tissue to bone, comprising:

inserting a first anchor through the soft tissue, wherein the first anchor comprises a length of an elongated flexible member secured to the first anchor prior to insertion;

inserting the first anchor into the bone;

passing the length of the elongated flexible member over the soft tissue; and

securing, after said step of passing, the length of the elongated flexible member to a second anchor, wherein the second anchor is a knotless fixation device comprising a cannulated interference device and an implant containing an aperture, the aperture being configured to capture the elongated flexible member, and wherein the step of securing the elongated flexible member further comprises:

passing the elongated flexible member through the aperture of the implant;

inserting the elongated flexible member and the implant into the hole; and

advancing the cannulated interference device toward a proximal end of the implant, to engage and lock in the implant with the elongated flexible member in the hole.

12. The method of claim 11, wherein said step of securing the length of the elongated flexible member comprises, in order:

inserting the second anchor with the length of the elongated flexible member coupled thereto into the bone;

tensioning the length of the elongated flexible member; and

securing the length of the elongated flexible member to the second anchor.

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13. The method of claim 12, wherein the step of inserting the second anchor comprises inserting the anchor directly into the bone without the anchor passing through the soft tissue.

14. The method of claim 11, wherein the step of securing the elongated flexible member to the second anchor is performed without tying any knots.

15. The method of claim 11, wherein the second anchor is a press-in suture anchor.

16. The method of claim 11, wherein the second anchor is a suture anchor with a swivel implant.

17. A knotless method of attaching soft tissue to bone, the method comprising:

inserting a first, second, and third anchor into the bone; fixedly securing a first length of a flexible elongated member over the soft tissue to the first and second anchors; and

fixedly securing a second length of the flexible elongated member over the soft tissue to the first and third anchors, wherein at least one of the first and third anchors is a knotless fixation device comprising a cannulated interference device and an implant containing an aperture, the aperture being configured to capture the second length of the elongated flexible member, and wherein the step of securing the elongated flexible member further comprises:

passing the second length of the elongated flexible member through the aperture of the implant;

inserting the second length of the elongated flexible member and the implant into the hole; and

advancing the cannulated interference device toward a proximal end of the implant, to engage and lock in the implant with the second length of the elongated flexible member in the hole.

18. The method of claim 17, wherein the first anchor is positioned beneath the soft tissue and the second and third anchors are positioned laterally to the soft tissue.

19. The method of claim 17, wherein the first and second lengths of the elongated flexible member are fixedly secured to the first anchor prior to insertion into the bone.

20. A knotless method of attaching soft tissue to bone, comprising:

inserting a first anchor with a length of an elongated flexible member attached thereto through the soft tissue;

inserting the first anchor into the bone;

inserting a second anchor with no suture attached thereto into bone;

passing the length of the elongated flexible member over the soft tissue; and

fixedly securing the length of the elongated flexible member to the inserted second anchor.

21. The method of claim 20, further comprising, after inserting the first anchor into the bone, fixedly securing the attached length of the elongated flexible member to the first anchor.

22. The method of claim 20, wherein the step of fixedly securing the attached length of the elongated flexible member to the first anchor is performed without tying any knots.

23. The method of claim 20, further comprising the step of tensioning the elongated flexible member prior to the step of fixedly securing the elongated flexible member to the first anchor.

24. The method of claim 23, wherein the step of tensioning the flexible elongated member comprises grasping the length of the flexible elongated member and pulling.

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25. A method of attaching soft tissue to bone, comprising:
 providing a first medial row constructed with a first plural-
 ity of fixation devices, wherein the at least one of the first
 plurality of fixation devices is an anchor;
 providing a second lateral row constructed with a second 5
 plurality of fixation devices, wherein the at least one of
 the second plurality of fixation devices is a knotless
 fixation device comprising a cannulated interference
 device and an implant containing an aperture, the aper-
 ture being configured to capture a flexible member;
 providing an implant material adjacent the first medial row
 and adjacent the soft tissue;
 providing the flexible member attached to the first medial
 row; and
 passing the flexible member through the soft tissue and
 over a lateral portion of the soft tissue to form a structure 15
 of multiple passes of said flexible member over the soft
 tissue, wherein the step of forming the structure of mul-
 tiple passes further comprises:
 passing the flexible member through the aperture of the
 implant;

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inserting the flexible member and the implant into the hole;
 and
 advancing the cannulated interference device toward a
 proximal end of the implant, to engage and lock in the
 implant with the flexible member in the hole.

26. The method of claim 25, wherein the implant material
 is porous collagen impregnated with autogenous bone mar-
 row.

27. The method of claim 25, wherein the implant material
 is tendon allograft impregnated with autogenous bone mar-
 row.

28. The method of claim 1, wherein the implant is a swivel
 implant.

29. The method of claim 1, further comprising the steps of:
 preloading the cannulated interference device of the knot-
 less fixation device on a shaft of a driver; and
 inserting the cannulated interference device into the hole.

* * * * *

Exhibit 12

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United States District Court
Southern District of California

KFX MEDICAL CORPORATION,)

)
Plaintiff,)

vs.)

) Case No. 11-CV-1698 DMS
) Jury Trial/Day 3, PM Session
ARTHREX, INCORPORATED,) Monday, August 26, 2013
) Volume III-B
Defendant.)

Before the Honorable Dana M. Sabraw
United States District Judge

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1 that's not going to sacrifice the actual result of the
2 repair. So we want the tissue to stay on bone, we don't want
3 anything dangerous to happen, so you don't want anything to
4 rip through tissue, and you don't want the anchors to pop off
5 or break or pull out of bone, and so -- that would be
6 dangerous for the patient. So allowing that there's going to
7 be some yield in whatever construct you make -- because you
8 can't make it like God made it, perfectly -- you want it to
9 yield in a safe way; and so in this construct, the suture
10 slipping slightly on the anchor, if it's going to yield at
11 all -- and I'm not saying that it does or, you know, every
12 time or not -- but if it's going to yield, that's going to be
13 the place where it likely will yield before anything else
14 happens.

15 Q. When you say something -- I forget what you said --
16 damaging the tendon, would that maybe be the suture actually
17 kind of slicing through the tendon if too much load's put on
18 that or too much stress on it? Is that something you worry
19 about?

20 A. Yes. If it's over-tensioned, something bad is going to
21 happen. The -- and the weak link in that kind of a
22 construct, the first thing that's going to happen is that the
23 suture is going to slice through the tissue like a cheese
24 wire cuts through cheese, and that's going to be your first
25 place that that would fail.

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1 San Diego, California - Monday, August 26, 2013, 12:30 p.m.
2 THE COURT: We're back on the record with all
3 present. Counsel?

4 MR. DICKERSON: Thank you, your Honor.

5 (The witness, Neal ElAttrache, was previously sworn and
6 continued to testify.)

7 Direct Examination, cont'd

8 BY MR. DICKERSON: Q. A few more questions only,
9 Dr. ElAttrache. When we were doing that demonstration -- and
10 I point out that I said we -- when we were doing that
11 demonstration, Doctor, when did the suture become secured to
12 the bone? Was it simultaneously with the insertion or some
13 other -- of the anchor body or some other time?

14 A. It's simultaneous with the insertion of the anchor.

15 Q. Now, in the suture wedge between the PushLock or
16 SwiveLock anchor and the bone, does that ever slip some?

17 A. It can -- it can creep a little bit; it can slip a little
18 bit on occasion.

19 Q. Is there occasion when that can be of benefit?

20 A. Well, that method -- that mode of yielding of the
21 construct is -- you have to allow for that to happen almost
22 always, and so there's going to be some yield in any
23 construct that you make. And so the value and the benefit of
24 a certain technique or construct is allowing for that type of
25 yielding within the construct, that it needs to be in a way

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1 Q. Is your wedge-in approach safer than an anchor that
2 captures suture between two parts of the anchor itself?

3 A. You know, typically whenever you have -- you know, the
4 more moving or modular parts that you incorporate and put
5 together and fit together, the more chances for failure. So,
6 you know, I would say if you're looking at safety, you don't
7 want to have things that are -- whatever can be put together,
8 a surgeon's rule of thumb is, can come apart. And so
9 generally speaking, I think that this would be a safer --
10 ultimately safer because you don't have things that can pull
11 apart from each other as far as the device.

12 Q. Such as a metal cap pulling off of a metal anchor?

13 A. Yeah. Now, I'm not familiar with their actual
14 biomechanical strength of the thing, but, you know, you may
15 not have any yield in that construct either, and so, you
16 know, the -- you're not going to get necessarily suture able
17 to slide or settle in that kind of a device.

18 Q. Doctor, how do you feel about being the person who
19 brought SutureBridge and SpeedBridge to the doctors really
20 around the world?

21 A. Well, look, I've dedicated a big part of my life to --
22 maybe this seems like just one thing -- but I've dedicated a
23 big part of my life to that; and at the end of it all, I
24 guess if that's the only thing I can contribute to my field,
25 then I would humbly say that I would -- it had been an honor

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1 affirmed that finding. And again, that case was also 2009,
2 which was several years after Advanced Cardio.

3 So I think all of these cases are consistent with
4 what we've been telling your Honor and what you did say in
5 your remarks on Thursday, which this is really just a
6 discretionary issue. And in a case like this -- and we
7 pointed your Honor to the Retractable Technologies case from
8 the Eastern District of Texas. In a case like this where the
9 claims are willful infringement and where the defendant is
10 putting on a case of independent development and the patent
11 is a part of that -- part of that defense of independent
12 development and what the defendant's intent was, it is
13 absolutely relevant evidence that should be permitted.

14 THE COURT: What about the argument that Arthrex
15 never relied on this either from its opinion counsel, David
16 Gaskey, or Mr. Schmieding?

17 MS. WOODWORTH: With respect to Mr. Gaskey, we do
18 not dispute that he did not rely on it. His opinions, which
19 really did focus much more on whether or not there's direct
20 infringement, he did not rely on it, and so we would not have
21 -- if Mr. Gaskey were to testify, he would not have anything
22 to say about the SutureBridge patent.

23 With respect to Mr. Schmieding, we think that
24 that's a different issue. The particular snippets of
25 testimony which KFx had submitted, their brief actually -- I

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1 know. And the SutureBridge patent, issuing after the KFx
2 patent, is very similar to I think that fact where, you know,
3 there's changes in fact or there's a change in the governing
4 law, and it's just an additional fact that you have to go
5 back and recheck your original reliance.

6 THE COURT: All right. Mr. Jennings?

7 MR. JENNINGS: I need to address the last one
8 first, your Honor. That was a misstatement in our brief;
9 when we said after the '311 patent issued in September 2011,
10 we meant to say after this lawsuit was filed in September of
11 2011. And Mr. Schmieding was asked about that, what did he
12 do, what did he rely upon, and the patent didn't come up.
13 And we would have one confusing foray into facts if we're
14 getting into a patent that issued during the course of this
15 lawsuit. So during the course of this lawsuit, Mr.
16 Schmieding is being represented by, you know, very competent
17 patent counsel in the litigation, he's got Mr. Gaskey giving
18 him opinions, and if we're going to then get into his
19 consideration of a later-issued patent on a later-filed
20 allocation as a basis to avoid willfulness that issued during
21 the course of the lawsuit, it is incredibly confusing, and --
22 I mean we're going to debate -- if it comes in, we're going
23 to be debating patent law and I'll be cross-examination --
24 examining about dominant patents and the law school examples,
25 and -- I think that's all I have to say.

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1 think it misstated, but it said that he was testifying about
2 after the '311 patent issued in September 2011. The '311
3 patent actually issued in September of 2009, and at that
4 point, of course Mr. Schmieding could not have relied on the
5 SutureBridge patent because it had not yet issued. And so
6 the point again here is when they ask a specific question
7 about what did you rely on when the '311 patent had issued,
8 he gave the entirety of his answer; he told them exactly what
9 he thought in September 2009, you know, led to his belief
10 that there was not infringement. But that's a different
11 question about whether or not at a subsequent point in time
12 when the SutureBridge patent was thereafter issued, whether
13 or not he could then in addition rely on that as further
14 evidence of why the SutureBridge procedure is different than
15 the KFx patent.

16 THE COURT: But wouldn't willfulness be measured at
17 the earlier point in time?

18 MS. WOODWORTH: I think that they're continuing to
19 assert that we are continuing to willfully infringe, we are
20 continuing to induce infringement; so I think that these are
21 all continuing torts. And it's very similar to your Honor's
22 claim construction. We actually -- Mr. Gaskey did a
23 supplemental opinion. It's just kind of one additional fact.
24 You know, he then -- Mr. Schmieding and Mr. Gaskey then had
25 to take into account your claim construction opinion, you

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1 THE COURT: Okay. The tentative would be to grant
2 or sustain KFx's objection to the '174 patent, but I'd like
3 to -- I apologize for not getting the briefing. I'm not sure
4 what's happening. I don't have it. What I'll do is read it
5 between now and 3:00 and then when we do the jury instruction
6 conference, I'll come back to it. But seems to me ultimately
7 that the -- for the reasons set forth in the KFx briefing and
8 just reiterated by Mr. Jennings, that there's a host of
9 problems with the '174 patent coming in. Any --

10 MS. WOODWORTH: And just a couple of very brief
11 comments on that, your Honor. And first, I think, just to
12 make clear that, again, the lawsuit was filed prior to the
13 SutureBridge patent issuing. So again, to the extent that a
14 question was directed to what Mr. Schmieding did when the
15 lawsuit was filed, he did not yet have -- Arthrex did not yet
16 have the SutureBridge patent, so it would not have been
17 appropriate to rely on it at that point as well.

18 The only -- the final point that I want to make is
19 that the SutureBridge patent was actually, with its entire
20 prosecution history, was actually originally produced by KFx
21 in this litigation. It's been a part of the record
22 throughout the entirety. They actually did question Mr.
23 Schmieding at his deposition about the application, about the
24 patent. They also -- KFx also originally had it on its
25 exhibit list, at least the application that led to the

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1 believes that there should be a separate -- since we're
2 adding a -- because we have a direct infringement instruction
3 and an indirect infringement on the verdict, we should have a
4 separate instruction, and in fact both parties submitted a
5 direct infringement instruction, which seems to not have made
6 its way in here. There's an instruction on inducing
7 infringement, and we probably should put right before that
8 the joint submission of instruction number 7.

9 THE COURT: It's instruction number 7?

10 MR. TAMBURRO: Yeah, I believe that was instruction
11 number 7 that was jointly submitted which covers direct
12 infringement.

13 THE COURT: I agree. It's not in here? Okay. You
14 agree as well, don't you, Mr. Jennings?

15 MR. JENNINGS: Yes, your Honor.

16 THE COURT: Okay.

17 MR. JENNINGS: I missed that.

18 THE COURT: I'm not sure what happened to that. It
19 fell out somewhere. Okay. What else?

20 MR. TAMBURRO: I think there might be -- on the
21 inducing patent infringement instruction, there might be just
22 a misstatement here. I'm told by someone who knows this area
23 of law a little better than I do that on the second to last
24 paragraph, the "to find willful blindness" paragraph, the
25 last word, instead of "avoid learning of the patent" should

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1 be "avoid learning of the infringement." I think that's just
2 an error.

3 THE COURT: Do you agree, Mr. Jennings?

4 MR. JENNINGS: Yes, I think that's fine.

5 THE COURT: I think so too. It came from a pattern
6 instruction, so -- I'll take a look at it, but I think
7 Arthrex is correct. Okay. What else?

8 MR. TAMBURRO: And we may have already caught this;
9 I apologize if we did, but on summary of invalidity defenses,
10 there is a paragraph on written description that should be
11 taken out.

12 THE COURT: Yes, I've got that. Anything else?

13 MR. TAMBURRO: Other than that we're fine with it.
14 Thank you, your Honor.

15 THE COURT: All right. So I'll make all of the
16 proposed changes, I'll reserve on the claim construction for
17 the case on the inserting issue. Other than that I'll make
18 the proposed changes, and I'll provide a set, clean set of
19 the verdict form and jury instructions to counsel tomorrow,
20 and then we can perfect the instructions tomorrow afternoon.

21 On the request by KFx to exclude the reference to
22 the '174 patent, I'm going to stand on the tentative. I did
23 read the surreply, and I agree with Mr. Jennings that
24 reference to that patent would raise a host of 403 concerns
25 and that any relevance would be substantially outweighed by

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1 undue or unfair prejudice and confusion of issues.

2 On the Rule 50(a) motions, I'm going to deny
3 without prejudice all of them. Those motions will be
4 preserved for any Rule 50(b) motions. Ultimately I do
5 believe there's sufficient evidence, construed most favorably
6 to KFx, to warrant the jury's consideration of all the
7 issues.

8 I think some of these issues are a real horse race
9 and the jury ought to fairly consider -- consider the issues.
10 And for the reasons set out by Mr. Jennings, I think it's --
11 viewing that evidence most favorably to KFx, there is
12 sufficient evidence for the jury to consider infringement,
13 direct infringement, inducement, willfulness, and I'll for
14 those reasons deny without prejudice.

15 MR. SABER: Your Honor, if I could just make one
16 comment on --

17 THE COURT: Yes.

18 MR. SABER: -- the willfulness part of it. There
19 had been debate before the trial as to -- on the objective
20 standard as to whether the -- which is ultimately for the
21 Court of course -- as to whether the Court should make that
22 ruling before it goes to the jury, and I would ask permission
23 to -- and I'm sure we're going to -- renew our motions on
24 every ground --

25 THE COURT: Right.

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1 MR. SABER: -- at the end of the case, but
2 particularly as it goes to willfulness because that really
3 was in debate, that we ask in particular on that one that
4 that may be the appropriate time. If the Court believes from
5 what it's heard that the objective standard has not been met,
6 it might be the appropriate thing not to send that to the
7 jury.

8 THE COURT: That would be Arthrex's request?

9 MR. SABER: Yes. Yes, your Honor.

10 THE COURT: All right. And your preference would
11 be that it go to the jury, and then the Court --

12 MR. JENNINGS: And then the Court exercises its
13 obligation authority to make that ruling.

14 THE COURT: All right. I'll probably go with the
15 latter. In these close cases it's often nice to get the
16 jury's point of view and then to -- for the Court to evaluate
17 all the issues in light of that. And that's one of the
18 reasons why I set up the verdict form the way I did is I
19 think it's possible the jury could find infringement but
20 there was no induced infringement; that's a different or
21 difficult standard. So I'll contemplate that more, but I'll
22 probably lean toward giving it to the jury and then deciding.

23 MR. SABER: And, your Honor, one other just
24 clarification on the motion about the '174 patent, I know we
25 had the colloquy before we left that that would also cover